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IMPACT OF PROPOSED BUDGET ON HEALTH RESEARCH

HEARING

BEFORE A

SUBCOMMITTEE OF THE

COMMITTEE ON APPROPRIATIONS

UNITED STATES SENATE

NINETY-NINTH CONGRESS

SECOND SESSION

SPECIAL HEARING

NONDEPARTMENTAL WITNESSES

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IMPACT OF PROPOSED BUDGET ON HEALTH RESEARCH

FRIDAY, APRIL 11, 1986

U.S. SENATE,
SUBCOMMITTEE OF THE COMMITTEE ON APPROPRIATIONS,
Washington, DC.

The subcommittee met at 9:11 a.m., in room SD–116, Dirksen Senate Office Building, Hon. Lowell P. Weicker, Jr. (chairman) presiding.

Present: Senators Weicker, Hatfield, Specter, and Inouye.

NONDEPARTMENTAL WITNESSES

STATEMENT OF DR. SAMUEL THIER, PRESIDENT OF THE INSTITUTE OF MEDICINE, NATIONAL ACADEMY OF SCIENCES

Senator WEICKER. This morning, the subcommittee will hear testimony from eight highly distinguished members of the biomedical research community. I have called this special hearing because I am deeply concerned about the impact of the President's budget cuts on biomedical research.

The President's 1987 budget request for the National Institutes of Health is $400 million less than what Congress appropriated in 1986. The President's request is a full $800 million less than what NIH tells us it needs in 1987 to continue its current level of research effort.

The administration claims its proposed cuts will result in savings for the year 1987, but there are no savings to be achieved by cutting the NIH budget.

The cost of such budget cuts in the out years will be enormous and we cannot afford it either in the dollars it will cost us or in the lives of those whose pain and suffering and even death could have been avoided.

When the Senate turns to consideration of the fiscal year 1987 budget, I intend to offer an amendment to restore funding for biomedical research. My amendment will also restore the drastic cuts, and in some cases the total elimination of the Federal programs which help educate and train our nurses, doctors, and other health professionals.

Surely in a budget which can afford $43 billion for research and development in defense, we can afford $6 billion for the research that will lead to cures for cancer, acquired immune deficiency syndrome

[AIDS], Alzheimer's disease, mental illness, and a whole host of diseases and conditions we are faced with today.

It is truly my pleasure to welcome each of the scientists who have come this morning to discuss the impact of the proposed budget cuts on biomedical research. All eight panelists are well recognized for their enormous contributions in the field of biomedical research.

Dr. Roger Guillemin is a Nobel Prize winner and currently at the Salk Institute. Dr. Samuel Thier is president of the Institute of Medicine [IOM] of the National Academy of Sciences. Dr. Robert Butler, winner of the Pulitzer Prize, is former Director of the National Institute on Aging. Dr. Theodore Cooper, formerly Assistant Secretary of Health, is now vice chairman of the board of the Upjohn Co. Dr. Kenneth Shine is president-elect of the American Heart Association, and dean-designate of the UCLA Medical School.

Dr. John Durant is president of the Fox Chase Cancer Center. Dr. Herbert Pardes is chairman of the Department of Psychiatry at Columbia University, and a former Director of the National Institute of Mental Health. Dr. George Palade is a winner of the Nobel Prize for Medicine, and the 1986 Presidential Medal for Science.

We have divided the group into two panels. The first panel will be Dr. Guillemin, Dr. Thier, Dr. Butler, and Dr. Cooper.

Let me again thank you all for taking of your very busy schedules to come down here and testify before the committee. I can't think of anything more important to this Nation than what is under discussion here this morning. Maybe it is that the Nation will start to listen to those that have the expertise and the commitment in the business of life.

I just want to alert everybody that we are going to be voting during the course of this session, unfortunately. Usually on Friday, we don't have votes, certainly not in the morning. It is going to be the case, and it is going to be a little bit disruptive. I apologize for that, but there is nothing to be done about it.

I would suggest again that everybody's prepared statement, in its entirety, will be included in the record. Having made that opening statement, it is just a great pleasure for me to be here with all of you, and to listen.

Do you have some batting order, or is Dr. Thier going to lead it off?

Dr. THIER. I am Dr. Samuel Thier, president of the Institute of Medicine at the National Academy of Sciences, and I welcome this opportunity to testify on the budget of the NIH for fiscal year 1987.

All budget discussions these days are necessarily conducted in the context of concern about the deficit, and although that concern is well placed, it should be joined by concern about the long-term economic and human costs of budget shaping actions based on arbitrary formulas or inadequate analysis.

The NIH budget proposed for fiscal year 1987 reduces expenditures in actual as well as constant dollars. Informed of the constraints necessary on next year's spending, NIH has replied with the utmost. It has sought to maximize scientific productivity by emphasizing funding of

individual grant proposals and establishing a new criterion of stabilized support, the maintenance of at least 18,000 grants at any time.

That strategy, however, was at the expense of the average amount of funding per grant, the number of research centers funded, the number of trainees supported, and the extent to which NIH can improve university flexibility, administrative support, and facility.

I might differ with some of the priorities chosen by the NIH, but they have made a credible response to what I view as stringent constraints. My concern is whether the constraints themselves are prudent.

The NIH is the primary source of support for basic biomedical research in the United States. The responsible conduct of research has been accepted in our society as innately good. It is a reflection of modern man's inquisitiveness and creativity, and it is also recognized as essential for a technologically advanced society like ours to continue its advances and maintain its competitiveness.

Basic research by definition does not make a product that can be used to support it. This has been recognized in the past both by the legislative and the executive branches of Government in their funding decisions. Even next year's budget in research in areas other than biomedical attests to that understanding. Why then is the NIH budget reduced?

A budget for the conduct of basic biomedical research could responsibly be reduced if the goals of that research are no longer valued as highly, if the return on past investment is felt to be inadequate, if there is too little promise of return on investment in the future, or if the research enterprise is inefficient or mismanaged. If none of these criteria are met, it seems fair to assume that the budget reductions primarily reflect an attempt to save money in the short run.

Saving money in a time of budget deficits is prudent unless there is good reason to believe that the long-range losses from the lack of investment far outweigh the short-term savings.

Looking at those criteria, surely the value of the research conducted by the NIH cannot be assumed to be less than that in the other basic sciences. Is the Federal Government now to diminish its commitment to research that contributes to improving the quality of life, reducing the burden of illness, preventing disease, and extending life span? I certainly hope not.

Funding could not reasonably have been reduced because the NIH investment has failed to pay adequate dividends—the prevention of polio and hepatitis, the reduction of infant mortality, improvement in cancer survival, and reductions in deaths from coronary heart disease, are only a few examples to the contrary. In the long run, such research saves both lives and money. Even the advancing medical technology being blamed for higher costs of care may produce savings.

The NIH budget could be reduced if the opportunities for future research payoffs seem less promising. But there is no reason to believe that payoffs of research supported by NIH will dwindle. The opportunity for biomedical research has never been greater.

The neurosciences have new insights into muscular dystrophy, the treatment of multiple sclerosis, brain and spinal cord regeneration, and even transplantation of brain tissue. Studies of the oncogenes have enormous potential for the diagnosis of cancer, the assessment of environmental triggers of malignancy and, hopefully, the ultimate understanding of malignancy.

Diabetes mellitus is yielding to new insights, some provided by modern immunology, and the field of immunology itself is exploding. Advances in molecular biology promise that gene therapy will be a reality in the near future. All of these and more contribute to knowledge pressingly needed to meet the challenges of our aging population.

If any further evidence of the value of pure basic research and its future promise were necessary, we need only look at AIDS. NIH-funded scientists identified the causative virus of the acquired immune deficiency syndrome in an amazingly short time after the disease was first recognized.

Our ability to define the causative agent and to diagnose exposure to it form the basis for attempts to control and prevent the disease. The basic insights upon which AIDS research is founded were the products of pure basic research conducted at a time when the disease AIDS was totally unknown.

Another more general consequence of NIH research is that it, as a byproduct of its mission, has spawned the swiftly growing biotechnology industry.

Basic biomedical research can be an expensive undertaking. Yet the NIH has established a record of prudent management of resources that should draw particularly loud plaudits in these times of fiscal worry. A study by the Institute Committee, 2 years ago, concluded that "none of the research organizations we investigated in the United States or abroad has a more effective structure for mobilizing scientific research against disease."

What I have just presented should be cause for great concern. Here is an organization carrying out the wishes of its constituency, scoring successes and appearing likely to have even greater success in the future, improving the well-being of humanity, and managing its enterprise well. A reduction in the budget of NIH can only be seen as a short-term deficit-reducing act with enormous long-term risks. Such action is hard to defend.

What conclusion can I reach?

The budget should enable not only stabilization of investigator research grants, but should also permit the development of a balanced portfolio, including, for example, the proper number of categorical centers needed to capitalize on otherwise uncoordinated research observations.

The budget should take into account the entire enterprise can come to a halt if there are no new investigators to provide innovative ideas. NIH should be able to determine which mechanisms of support are most efficient and productive in training investigators, but the required flexibility is not in the proposed budget.

Please keep in mind what we have for years that young investigators frightened off by wide swings in support cannot be returned to the laboratories as easily as money can be returned to the budget. A sense of stability and commitment to basic research is important beyond a pledge of a certain number of dollars.

I mentioned universities earlier, and I would like to come back to them because NIH funding is so crucial to their conduct of biomedical research.

Universities are a resource that cannot be duplicated and must not be allowed to deteriorate. That is not only my opinion but also the conclusion recently announced by the White House Science Council Panel headed by David Packard and Allan Bromley. They emphasize the importance of university-based research and of the university-Government partnership.

That partnership includes an understanding that indirect cost reimbursement for administration of grants should only be reduced if the administrative burden is reduced. Forcing cost sharing on already hard-pressed universities can only be damaging to the strength of their partnership with Government.

The universities need some flexibility in managing complex research projects, and yet the proposed NIH budget would reduce the biomedical research support grants provided to the universities. It would perpetuate the Government proposal to limit the payment for indirect cost of research without invoking the complementary recommendations of the White House Science Council Panel. It would reduce to zero the construction funds associated with research projects, and the biomedical research laboratories and equipment of universities are in need of repair and replacement. To budget for no improvement in facilities or equipment in fiscal year 1987 does not seem a sensible investment policy.

In summary, the NIH budget strikes me as inconsistent with the Federal Government's expressed commitments to the support of basic research. The particular value of basic biomedical research, with its implications for health and for control of health costs, makes a compelling argument against cutting the NIH budget.

It is hard to understand who is served by that cut. If your conclusion is as mine, that no one is well-served, I would respectfully encourage you to restore the NIH budget at least to parity with the rest of the investment in defense and nondefense basic sciences described in the 1987 budget. If you feel that potential payback on investment in the NIH is likely to exceed the investment itself—as it has done historically—then I would encourage you to consider additional support.

Thank you very much for the opportunity.

PREPARED STATEMENT

Senator WEICKER. Thank you, Dr. Thier. We will be back for questions after everybody has testified.

[The statement follows:]

STATEMENT OF DR. SAMUEL O. THIER

I AM DR. SAMUEL O. THIER, PRESIDENT OF THE INSTITUTE OF MEDICINE OF THE NATIONAL ACADEMY OF SCIENCES AND I WELCOME THIS OPPORTUNITY TO TESTIFY ON THE BUDGET OF THE NATIONAL INSTITUTES OF HEALTH FOR FISCAL YEAR 1987. ALL BUDGET DISCUSSIONS THESE DAYS ARE NECESSARILY CONDUCTED IN A CONTEXT OF CONCERN ABOUT THE DEFICIT. ALTHOUGH THAT CONCERN IS WELL PLACED, IT SHOULD BE JOINED BY CONCERN ABOUT THE LONG-TERM ECONOMIC AND HUMAN COSTS OF BUDGET-SHAPING ACTIONS BASED ON ARBITRARY FORMULAS OR INADEQUATE ANALYSIS.

THE NIH BUDGET PROPOSED FOR FY 1987 REDUCES EXPENDITURES IN ACTUAL AS WELL AS CONSTANT DOLLARS. INFORMED OF THE CONSTRAINTS NECESSARY ON NEXT YEAR'S SPENDING, NIH HAS REPLIED WITH THE UTMOST RESPONSIBILITY. IT HAS SOUGHT TO MAXIMIZE SCIENTIFIC PRODUCTIVITY BY EMPHASIZING FUNDING OF INDIVIDUAL GRANT PROPOSALS AND ESTABLISHING A NEW CRITERION OF STABILIZED SUPPORT: MAINTENANCE OF AT LEAST 18,000 GRANTS AT ANY GIVEN TIME. THOSE CHOICES, HOWEVER, WERE MADE AT THE EXPENSE OF THE AVERAGE AMOUNT OF FUNDING PER GRANT, THE NUMBER OF RESEARCH CENTERS FUNDED, THE NUMBER OF TRAINEES SUPPORTED, AND THE EXTENT TO WHICH NIH CAN IMPROVE UNIVERSITY FLEXIBILITY, ADMINISTRATIVE SUPPORT, AND FACILITIES. I MIGHT DIFFER WITH SOME OF THE PRIORITIES CHOSEN BY NIH, BUT THEY HAVE MADE A CREDIBLE RESPONSE TO WHAT I VIEW AS STRINGENT CONSTRAINTS. MY CONCERN IS WHETHER THE CONSTRAINTS ARE PRUDENT.

THE NIH IS THE PRIMARY SOURCE OF SUPPORT FOR BASIC BIOMEDICAL RESEARCH IN THE UNITED STATES. THE RESPONSIBLE CONDUCT OF RESEARCH HAS BEEN ACCEPTED BY OUR SOCIETY AS INNATELY GOOD, A REFLECTION OF MODERN MAN'S INQUISITIVENESS AND CREATIVITY. SUCH RESEARCH ALSO IS RECOGNIZED AS ESSENTIAL FOR A TECHNOLOGICALLY ADVANCED SOCIETY LIKE OURS TO CONTINUE ITS ADVANCES AND MAINTAIN ITS COMPETITIVENESS. BASIC RESEARCH BY DEFINITION DOES NOT MAKE A PRODUCT THAT CAN BE USED TO SUPPORT IT. THIS HAS LONG BEEN RECOGNIZED BOTH BY THE LEGISLATIVE AND EXECUTIVE BRANCHES OF GOVERNMENT IN THEIR FUNDING OF IT IN THE PAST. EVEN NEXT YEAR'S BUDGET IN RESEARCH AREAS OTHER THAN

BIOMEDICAL ATTESTS TO THAT UNDERSTANDING. WHY THEN IS THE NIH BUDGET TO BE REDUCED?

A BUDGET FOR THE CONDUCT OF BASIC BIOMEDICAL RESEARCH COULD RESPONSIBLY BE REDUCED IF THE GOALS OF THAT RESEARCH ARE NO LONGER VALUED AS HIGHLY, IF THE RETURN ON PAST INVESTMENT IS FELT TO BE INADEQUATE, IF THERE SEEMS TO BE TOO LITTLE PROMISE OF RETURN ON INVESTMENT IN THE FUTURE, OR IF THE RESEARCH ENTERPRISE IS INEFFICIENT OR MISMANAGED. IF NONE OF THESE CRITERIA ARE MET IT SEEMS FAIR TO ASSUME THAT BUDGET REDUCTIONS PRIMARILY REFLECT AN ATTEMPT TO SAVE MONEY IN THE SHORT RUN. SAVING MONEY IN A TIME OF BUDGET DEFICIT IS PRUDENT UNLESS THERE IS GOOD REASON TO BELIEVE THAT THE LONG-RANGE LOSSES FROM THE LACK OF INVESTMENT FAR OUTWEIGH THE SHORT-TERM SAVINGS.

SURELY THE VALUE OF THE RESEARCH CONDUCTED BY THE NIH CANNOT BE ASSUMED TO BE LESS THAN THAT IN THE OTHER BASIC SCIENCES. IS THE FEDERAL GOVERNMENT NOW TO DIMINISH ITS COMMITMENT TO RESEARCH THAT CONTRIBUTES TO IMPROVING THE QUALITY OF LIFE, REDUCING THE BURDEN OF ILLNESS, PREVENTING DISEASE, AND EXTENDING THE LIFE SPAN?

FUNDING COULD NOT REASONABLY HAVE BEEN REDUCED BECAUSE THE NIH INVESTMENT HAS FAILED TO PAY ADEQUATE DIVIDENDS--PREVENTION OF POLIO AND HEPATITIS, REDUCTION OF INFANT MORTALITY, IMPROVEMENT IN CANCER SURVIVAL, AND REDUCTION IN DEATHS FROM CORONARY HEART DISEASE, ARE ONLY A FEW EXAMPLES TO THE CONTRARY. IN THE LONG RUN, SUCH RESEARCH SAVES BOTH LIVES AND MONEY. EVEN THE ADVANCING MEDICAL TECHNOLOGY BEING BLAMED FOR HIGHER COSTS OF CARE MAY PRODUCE SAVINGS.

THE NIH BUDGET COULD BE REDUCED IF OPPORTUNITIES FOR FUTURE RESEARCH PAYOFFS SEEM LESS PROMISING. BUT THERE IS NO REASON TO BELIEVE THAT PAYOFFS OF RESEARCH SUPPORTED BY NIH WILL DWINDLE. THE OPPORTUNITY FOR BIOMEDICAL SCIENCES HAS NEVER BEEN GREATER. THE NEUROSCIENCES HAVE NEW

INSIGHTS INTO MUSCULAR DYSTROPHY, THE TREATMENT OF MULTIPLE SCLEROSIS, BRAIN AND SPINAL CORD REGENERATION, AND EVEN THE POSSIBILITY OF TRANSPLANTING BRAIN TISSUE. STUDIES OF ONCOGENES HAVE ENORMOUS POTENTIAL FOR THE DIAGNOSIS OF CANCER, THE ASSESSMENT OF ENVIRONMENTAL TRIGGERS OF MALIGNANCY AND THE ULTIMATE UNDERSTANDING OF THE BIOLOGY OF MALIGNANCY. DIABETES MELLITUS IS YIELDING TO NEW INSIGHTS SOME PROVIDED BY MODERN IMMUNOLOGY; THE FIELD OF IMMUNOLOGY ITSELF IS EXPLODING WITH DISCOVERIES; ADVANCES IN MOLECULAR BIOLOGY PROMISE THAT GENE THERAPY WILL BE A REALITY IN THE NEAR FUTURE; ALL OF THESE AND MORE CONTRIBUTE TO KNOWLEDGE PRESSINGLY NEEDED TO MEET THE CHALLENGE OF OUR AGING POPULATION.

IF ANY FURTHER EVIDENCE FOR THE VALUE OF PURE BASIC RESEARCH AND ITS FUTURE PROMISES WERE NECESSARY, WE NEED ONLY LOOK AT AIDS. NIH-FUNDED SCIENTISTS IDENTIFIED THE CAUSATIVE VIRUS OF THE ACQUIRED IMMUNE DEFICIENCY SYNDROME IN AN AMAZINGLY SHORT TIME AFTER THE DISEASE WAS FIRST RECOGNIZED. OUR ABILITY TO DEFINE THE CAUSATIVE AGENT AND TO DIAGNOSE EXPOSURE TO IT, FORM THE BASIS FOR ATTEMPTS TO CONTROL AND PREVENT THE DISEASE. THE BASIC INSIGHTS UPON WHICH AIDS RESEARCH IS FOUNDED WERE THE PRODUCTS OF PURE BASIC RESEARCH CONDUCTED AT A TIME WHEN THE DISEASE AIDS WAS TOTALLY UNKNOWN. ANOTHER MORE GENERAL CONSEQUENCE OF NIH RESEARCH IS THAT IT SPAWNED THE SWIFTLY GROWING BIOTECHNOLOGY INDUSTRY AS A BYPRODUCT OF ITS MISSION.

BASIC BIOMEDICAL RESEARCH CAN BE AN EXPENSIVE UNDERTAKING. YET NIH HAS ESTABLISHED A RECORD OF PRUDENT MANAGEMENT OF RESOURCES THAT SHOULD DRAW PARTICULARLY LOUD PLAUDITS IN THESE TIMES OF FISCAL WORRY. A STUDY BY AN INSTITUTE OF MEDICINE COMMITTEE TWO YEARS AGO CONCLUDED THAT "NONE OF THE RESEARCH ORGANIZATIONS WE INVESTIGATED IN THE UNITED STATES OR ABROAD HAS A MORE EFFECTIVE STRUCTURE FOR MOBILIZING SCIENTIFIC RESEARCH AGAINST DISEASE."

WHAT I'VE JUST PRESENTED SHOULD BE CAUSE FOR GREAT CONCERN. HERE IS AN ORGANIZATION CARRYING OUT THE WISHES OF ITS CONSTITUENCY, SCORING SUCCESSES

AND APPEARING LIKELY TO HAVE EVEN GREATER SUCCESS IN THE FUTURE, IMPROVING THE WELL-BEING OF HUMANITY, AND MANAGING ITS ENTERPRISE WELL. A REDUCTION IN THE BUDGET OF NIH CAN ONLY BE SEEN AS A SHORT-TERM DEFICIT-REDUCING ACT WITH ENORMOUS LONG-TERM RISKS. SUCH ACTION IS HARD TO DEFEND.

WHAT CONCLUSION CAN I REACH?

THE BUDGET SHOULD ENABLE NOT ONLY STABILIZATION OF INVESTIGATOR-INITIATED RESEARCH GRANTS, BUT SHOULD ALSO PERMIT THE DEVELOPMENT OF A BALANCED PORTFOLIO INCLUDING, FOR EXAMPLE, THE PROPER NUMBER OF CATEGORICAL CENTERS NEEDED TO CAPITALIZE ON OTHERWISE UNCOORDINATED RESEARCH OBSERVATIONS. THE BUDGET SHOULD TAKE INTO ACCOUNT THAT THE ENTIRE ENTERPRISE CAN COME TO A HALT IF THERE ARE NO NEW INVESTIGATORS TO PROVIDE INNOVATIVE IDEAS. NIH SHOULD BE ABLE TO DETERMINE WHICH MECHANISMS OF SUPPORT ARE MOST EFFICIENT AND PRODUCTIVE IN TRAINING INVESTIGATORS, BUT THE REQUIRED FLEXIBILITY IS NOT IN THE PROPOSED BUDGET. PLEASE KEEP IN MIND THAT YOUNG INVESTIGATORS FRIGHTENED OFF BY WIDE SWINGS IN SUPPORT CANNOT BE RETURNED TO THE LABORATORIES AS EASILY AS MONEY CAN BE RETURNED TO THE BUDGET. A SENSE OF STABILITY AND COMMITMENT TO BASIC RESEARCH IS IMPORTANT BEYOND A PLEDGE OF A CERTAIN NUMBER OF DOLLARS.

I MENTIONED UNIVERSITIES EARLIER, AND I SHOULD COME BACK TO THEM, BECAUSE NIH FUNDING IS SO CRUCIAL TO THEIR CONDUCT OF BIOMEDICAL RESEARCH. UNIVERSITIES ARE A RESOURCE THAT CANNOT BE DUPLICATED AND MUST NOT BE ALLOWED TO DETERIORATE. THAT IS NOT ONLY MY OPINION BUT ALSO THE CONCLUSION RECENTLY ANNOUNCED BY A WHITE HOUSE SCIENCE COUNCIL PANEL HEADED BY DAVID PACKARD AND ALLAN BROMLEY. THEY EMPHASIZED THE IMPORTANCE OF UNIVERSITY-BASED RESEARCH AND OF THE UNIVERSITY-GOVERNMENT PARTNERSHIP. THAT PARTNERSHIP INCLUDES AN UNDERSTANDING THAT INDIRECT COST REIMBURSEMENT FOR ADMINISTRATION OF GRANT PROJECTS SHOULD ONLY BE REDUCED IF THE ADMINISTRATIVE BURDEN IS REDUCED. FORCING COST-SHARING ON ALREADY HARD-PRESSED UNIVERSITIES CAN ONLY BE DAMAGING TO THE STRENGTH OF THEIR PARTNERSHIP WITH

GOVERNMENT. THE UNIVERSITIES NEED SOME FLEXIBILITY IN MANAGING COMPLEX RESEARCH PROJECTS. YET THE PROPOSED NIH BUDGET WOULD REDUCE THE BIOMEDICAL RESEARCH SUPPORT GRANTS PROVIDED TO UNIVERSITIES. IT WOULD PERPETUATE THE GOVERNMENT'S PROPOSAL TO LIMIT PAYMENT FOR INDIRECT COSTS OF RESEARCH WITHOUT INVOKING THE COMPLEMENTARY RECOMMENDATIONS OF THE WHITE HOUSE SCIENCE COUNCIL PANEL. IT WOULD REDUCE TO ZERO CONSTRUCTION FUNDS ASSOCIATED WITH RESEARCH PROJECTS. THE BIOMEDICAL RESEARCH LABORATORIES AND EQUIPMENT OF UNIVERSITIES ARE IN NEED OF REPAIR AND REPLACEMENT; TO BUDGET FOR NO IMPROVEMENTS IN FACILITIES OR EQUIPMENT IN FY 1987 DOES NOT SEEM A SENSIBLE INVESTMENT POLICY.

IN SUMMARY, THE NIH BUDGET STRIKES ME AS INCONSISTENT WITH THE FEDERAL GOVERNMENT'S EXPRESSED COMMITMENTS TO THE SUPPORT OF BASIC RESEARCH. THE PARTICULAR VALUE OF BASIC BIOMEDICAL RESEARCH, WITH ITS IMPLICATIONS FOR HEALTH AND FOR THE CONTROL OF HEALTH CARE COSTS, MAKES A COMPELLING ARGUMENT AGAINST CUTTING THE NIH BUDGET. IT IS HARD TO UNDERSTAND WHO IS SERVED BY ITS CONSTRICTION. IF YOUR CONCLUSION IS AS MINE, THAT NO ONE IS WELL SERVED, I WOULD RESPECTFULLY ENCOURAGE YOU TO RESTORE THE NIH BUDGET AT LEAST TO PARITY WITH THE REST OF THE INVESTMENT IN DEFENSE AND NON-DEFENSE BASIC SCIENCES DESCRIBED IN THE 1987 BUDGET. IF YOU FEEL THAT POTENTIAL PAYBACK ON INVESTMENT IN THE NIH IS LIKELY TO EXCEED THE INVESTMENT ITSELF--AS IT HAS DONE HISTORICALLY--THEN I WOULD ENCOURAGE YOU TO CONSIDER ADDITIONAL SUPPORT.

I WOULD BE PLEASED TO RESPOND TO ANY QUESTIONS YOU MAY HAVE.

STATEMENT OF ROBERT N. BUTLER, M.D., PULITZER PRIZE WINNER AND FORMER DIRECTOR, NATIONAL INSTITUTE ON AGING

Senator WEICKER. Dr. Butler.

Dr. BUTLER. What I would like to do is submit for the record my more formal statement, and highlight some of the key issues, as I see them, from the perspective of science at large, biomedical research, and specifically aging research.

It is, in fact, a minimal position that I presented to you in the formal statement. NIA, the National Institute on Aging, has never been adequately capitalized, having come into being right after the Organization of Petroleum Exporting Countries [OPEC] price rises, and in a sense, it is now being decapitated, yet this is a period of time in which we must address the fundamental biological processes of aging, and particularly focus upon that most devastating of conditions, senile dementia of the Alzheimer's type, perhaps the No. 4 cause of death.

In fact, as a society, we have not adequately prepared for the longevity revolution. This extraordinary increase in less than a century, a gain of 25 years in life expectancy is nearly equal to what had been attained the preceding 5,000 years, something that we should feel very proud of. Yet, neither the private sector nor Government has responded adequately to it. We are losing many opportunities.

In 2030, which is after all just tomorrow, the baby boomers, born between 1946 and 1964, will by then constitute 21 percent of the population, which means that 21 percent of the population will be 65 and above, and will be made up by the baby boomers. The health costs associated with that group will be at least in excess of 50 percent.

The fear of losing one's mind, of losing one's independence, and having to go into a nursing home, is one of the most critical spectres that haunts people throughout their lives, and it becomes increasingly so as people grow older.

Today, the estimates are that we have about 2 million people suffering from senile dementia of Alzheimer's type, the costs being perhaps in the range of $38 billion in direct costs. But imagine 2050, when it is anticipated that we will have 9 million people with senile dementia of the Alzheimer's type, if there are not breakthroughs, that would cost us some $180 billion in direct costs, which is nearly equal to the present budget deficit.

Two of the great causes of death, as Dr. Thier pointed out, have been dramatically reduced in terms of deaths, death from stroke and death from heart disease. That reflects in no small measure the success of NIH. But we have not completed the task of understanding better cardiovascular disease, circulatory disease, and we certainly have before us the important problems of Alzheimer's disease and cancer.

It is clear that aging is one of the three great antecedents of disease, along with genetics and environment broadly defined, and yet we have spent so little energy, money, resources in studying the fundamental processes of aging. The 85-plus age group is now the fastest growing age group in all of the industrialized world. Some 24 percent of people over 85 reside in nursing homes.

Clearly we must solve this problem of Alzheimer's disease, and if we do, we will empty one-half of the nursing home beds in this country, one-half. I think of the nursing home as the iron lung of geriatrics, and I would remind us that our last polio epidemic was in 1961, just 25 years ago, that we no longer have a significant array of tuberculosis [TB] sanatoria. In short, biomedical research can make a successful effort.

Now we must also think in the broadest terms about biomedical science. We must refocus our energy upon research training, after all the life-blood of science. In fact, we really have to think about science education in public and private schools. We have to also focus upon the training of people in the field of geriatrics.

Despite the fact that we spent last year $2 billion in Medicare money for graduate medical education, really none of it was devoted to training in geriatrics. In this country, we have about 100 geriatrics fellowships, period, training people to become the leaders, the researchers, the innovators in health delivery to older people.

I am not talking about a new practicing specialty in geriatrics, I am talking about academic leadership. In the first 22 years of existence of the Heart Institute, it was able to train 16,000 people in cardiology, just to give you a standard against which to compare that small group of 100 geriatric fellowships.

To bring us to a conclusion, one of the most disturbing facts for so many of us, I believe, is the erosion of the science base in our country, of the science infrastructure, of the training of young people, of the creation of support for biotechnology and high technology, the loss of flexibility at NIH in pursuing many opportunities, to conduct clinical trials, to build critical resources through centers.

I personally believe that one of the key groups to look at in terms of the problem of aging are the baby boomers. The first baby boomer turned 40 somewhere about 1 second after midnight on January 1 of this year. That means the baby boomers, the largest generation in U.S. history, are beginning to appreciate the problems of their parents and their grandparents, who are now well into their sixties and eighties.

But I submit that we can't wait until 2020, when the baby boomers reach golden pond to begin to find options to nursing home care, to train academic geriatricians, to find the solution to Alzheimer's disease, and to look at the many other tremendously disturbing maladies of late life.

Thank you.

PREPARED STATEMENT

Senator WEICKER. Thank you, Dr. Butler. We will insert your statement in the record at this point.

[The statement follows:]

STATEMENT OF DR. ROBERT N. BUTLER

Mr. Chairman and Members of the Committee, I am Dr. Robert N. Butler. I am pleased to testify before you from a perspective that is somewhat unique. I served as the first Director of the National Institute on Aging (NIA) from 1976 until 1982. Since that time I have held the positions of Brookdale Professor of Geriatrics and Adult Development, and Chairman of the Gerald and May Ellen Ritter Department of Geriatrics and Adult Development at Mount Sinai School of Medicine. Therefore, I know first hand about the programs, priorities, and accomplishments of the National Institute on Aging from its infancy in 1976 to its position today as the preeminent agency for the support and conduct of aging research and research training in the Nation, if not the world. From my vantage point in academia, I can testify to the value of an agency such as the NIA which has the power and strength, if we would only fuel it, to turn around what is potentially a devastating trend within our country.

During the period I was Director of the Institute, I was fond of saying that it was fortuitous that the NIA was established at a time when it could create programs directed toward acquiring new biomedical knowledge about the aging process so that the impact of the graying of the baby boomers (those born between 1945 and 1955) could be turned into a triumph rather than a tragedy. At that point in time, although the problems associated with our elderly citizens were serious, they were still at a level which was manageable by the individuals affected, their families, and society. If the Institute had not been created at that time and research into the myriad of health problems that often face individuals as they grow older had not been intitiated and expanded, it was inevitable that these problems would have, in a relatively short period, outstripped the capacity of our society to handle them.

In recent months, my optimism has turned to pessimism. The trend in the financing of aging research, if the President's budget for FY 1987 is enacted, is a "hold-the-line" position. It is inappropriate to hold the line at this particular juncture of the Institute's development. Its programs are just beginning to unravel the mysteries of the etiology, diagnosis, and treatment of Alzheimer's disease for example. Much, much more needs to be done in this important area if we are to progress toward the day when this debilitating illness is overcome. Research on the application of new molecular genetic techniques to

the study of the aging process could eventually provide the best chance for understanding, and therefore being able to change, the aging process. The study of the oldest old (those over 85 years of age), the fastest growing segment of the U.S. population, is important in that this group has a very high rate of morbidity and disability and therefore places a heavy burden on our health care system. More knowledge about this age group may assist in extending the healthy and effective functioning of individuals more into the later years and therefore reducing the burden on society and the health care system.

The understanding of the normal aging process which is being acquired through such studies as the Baltimore Longitudinal Study of Aging is important to provide knowledge about what normal aging is and is not, so that the process of aging can be separated from disease. These are but a few examples of the types of research that are being supported and conducted by the Aging Institute. It is pure folly not to continue to expand the research programs of the National Institute on Aging. Not to do so is wrong from the point of view of society; it is wrong from the point of view of research; it is wrong from the point of view of economics; and it is wrong in terms of the future of the country.

Biomedical research, among many things, must be considered an investment in the future, and this is particularly true about research on aging. Studies have proven that for every dollar invested in research, society benefits as much as thirteen dollars - and this just in monetary terms. Nothing is included here to reflect the reduction in the pain and suffering of the victims and their families, both physical and mental. Based on the known growth of our population of older citizens over the next several decades, it would be extremely short-sighted and foolhardy not to make this investment in research on the costly health problems which, without intervention, will surely beset them. A ten percent reduction in the cost of caring for our elderly within the next ten years would save $10 billion annually. I am convinced that this goal is attainable! But, we need the foresight and courage to begin to make that investment now!!

Let me now describe several of the high priority activities of the NIA which present opportunities for progress in aging research and training.

At the time the Institute identified Alzheimer's disease as a high priority in 1976, there were only about ten grants throughout NIH supporting research in this area. This despite

the then-known fact that approximately some 1.5 million people suffered from this condition and many of them were institutionalized at great cost because of it. AD could not be diagnosed, prevented, treated, or cured and, therefore, there was a paucity of interest in researching it. Because of the interest generated by the Institute under the FY 86 revised budget, the Public Health Service will support $53.9 million in AD research, $32.1 million of it by the NIA. Although this ten-year research effort has not answered all of the earlier questions, we do now have better diagnostic methods and theories abound on ways to prevent, treat, or cure it. the development of improved neuropsychological test batteries, the detection of abnormal proteins in the blood, and the finding of specific genetic markers in familial cases are examples of advances in the diagnostic screening techniques for AD; modern molecular biology techniques hold great promise for helping find the causes of AD by determining what causes the formation of abnormal proteins in the blood, for example; and research in animals suggests that lost brain function may be restored through the transplantation of brain cells.

These are exciting findings, ones which were unthinkable just ten short years ago. These and many more developed through NIA-supported research illustrated the degree to which we can overcome what appear to be insurmountable problems if we have the will to commit the necessary resources.

The Alzheimer's Disease Research Centers Program provides an unparalleled opportunity in the field of AD research to translate research findings in improved care and diagnosis for Alzheimer's patients. This program was initiated just two years ago, and despite restricted and reduced funding which has caused delays in initiating some approved projects, is already contributing tremendously to the knowledge base related to this disease. But we must expand beyond the ten centers which now exist if we are not to lose momentum. Currently, approximately 2-3 million suffer from AD and it is estimated that this number will double by the year 2000. The Nation must be willing to pay now to overcome the problem or we are destined to pay later to care for the individuals who, without the intervention of our scientific community, will surely become victims.

To summarize my views upon Alzheimer's disease support, we should bring the present ten national Alzheimer's Disease Research Centers to full funding. This would require $2.3 million.

We should make available an additional $10 million for general funding of Alzheimer's disease research through investigator-initiated research projects and program projects.

We should also support five additional Alzheimer's Disease Research Centers at $1 million each which should be a total of $5 million.

Another important research area which must be conducted and expanded is that related to osteoporosis. Osteoporosis is a condition that affects as many as 15-20 million individuals in the Nation and costs approximately $2 billion a year to treat. One of its many sequalae is hip fractures with approximately two hundred thousand of them occurring each year. This condition, which affects primarily women, often occurs post-menopausally. The genesis of osteoporosis appears to relate to age-related bone thinning, diet (calcium and vitamin K), exercise and hormonal balance among other factors. I urge that the National Institute on Aging in coordination with the New National Institute of Arthritis, Muscular Skeletal and Skin Diseases create programs of excellence which focus attention upon this major condition. At the minimum, funding should be in the range of $7 million.

It would be impossible to continue the important agenda of research on aging without a continuing investment in research training. I urge a minimum of $200,000 devoted to support of fellows to work in the NIA intramural program. $1.1 million should go for career awards and $1.4 million should go for NRSA. This would bring the total for research training to $2.7 million.

It is of great importance that centers and clinical trials be supported not only at the National Institute on Aging but throughout the National Institutes of Health. The ultimate application of new knowledge must be tested. The systolic hypertention in the elderly patient program (SHEP) is a case in point. This program by the National Heart Lung and Blood Institute (NHLBI) and the NIA must be supported. The result will be the further effective reduction of death from heart disease and stroke.

I am pleased to have had this opportunity to present the case for the National Institute on Aging this morning. This Institute was born shortly after the impact of the OPEC rise in oil prices. This was the beginning of the era of austerity. The new National Institute

on Aging was never adequately capitalized. It never received an adequate supply of personnel to appropriately monitor the financial aspects of the grant program and to spearhead new initiatives. There should be a minimum of 20 additional FTE personnel provided to the Institute. This would cost $700,000.

As we move towards the end of the 20th century we must be mindful of the remarkable numbers of baby boomers born between 1946 and 1964 who would soon be among the ranks of those over 65. We cannot wait until they reach their maximum, roughly between 2020 and 2030, to develop the kind of new knowledge required to prevent and effectively treat the variety of diseases that afflict older people. From that perspective research on aging is the ultimate service and the ultimate cost containment.

STATEMENT OF DR. ROGER GUILLEMIN, WINNER OF THE NOBEL PRIZE FOR MEDICINE

Senator WEICKER. Dr. Guillemin.

Dr. GUILLEMIN. Senator, I am a physician, but I have worked in basic research all of my life. The last 30 years have been devoted to work in the laboratory. I received a Nobel Prize, as you indicated earlier, in 1977 for the research which has led us to understand that our brain makes hormones. We can now talk of brain hormones like for years we have been talking of sex hormones, hormones of the pancreas involving diabetes.

I would like to make some remarks around the written statement that was submitted to your committee.

I am also the incoming president of the Endocrine Society. The eradication of infectious diseases, medication involved with endocrinology, those have probably been the two aspects of modern medicine which have touched more hundreds of millions of people than any other aspects of medicine.

Probably the most important point I would like to make as a basic science man is that the public must understand that all the funding of basic medical research in this country, with the exception of the research conducted in industry and whatever parts of budgets come from private foundations, all of the budget, 95 percent of the budget of medical research, comes from Federal funding.

In other words, we are not asking, when we are concerned with the possible cuts of the budgets of research laboratories, we are not concerned with some sort of subsidies to make our life easier, or our equipment fancier, or our laboratories easier to live in. We are talking about the actual existence of biomedical research in this country.

This concept has to be emphasized over and over again so that the public understands. I will use the same words again, we are not looking for subsidies, we are looking for the problems involved in the survival of biomedical research.

Biomedical research is expensive. The first of these brain hormones, which I characterized with my collaborator, when I was still on the staff of Baylor College of Medicine in Houston, 18 or 20 years ago—the first of these molecules, making simple assumptions from what I read in the Houston Post in those days, meant that weight per weight the first kilogram of that new brain hormone was five times more expensive than a kilogram of Moon rock—a lot of money.

Nowadays, this same molecule, which is used, by the way, all over the world in hundreds of thousands of clinical tests all the time, is, through the efforts of pharmaceutical industry, available for fractions of a cent per active dose.

All of this is to say that biomedical research is expensive, but also can be brought to the public in unquestionable ways through the efforts of the pharmaceutical industry.

One of the important points that I want to mention here also has already been mentioned in more detail by Dr. Thier, and it is the extreme importance in the existence and future of biomedical research, and of all science, actually, of the stability of funding.

We are not trying to be unreasonable about it, but it is absolutely impossible to train people, and just lose them, see them disappear because we don't have the moneys to keep them in some position in a research laboratory, or in an institute.

It takes 5 to 7 years to train young people to become efficient in one aspect of research right now. Molecular biology, at this moment in particular, is probably the best example of this. We simply cannot consider an efficient series of programs in centers and in research institutions unless there is some modicum of stability in these research budgets.

It has also been mentioned that in the future, for these programs, which are being proposed, NIH may not have, the institutes of the NIH may not have the possibility of designing their own areas of emphasis. This, I think, would be a capital mistake. The institutes must be left to be responsible for what areas they want to put their money in.

The problem of the appraisal, the peer committee, and the appraisal of the various research proposals is still the best way to characterize the quality of science in this country.

I mentioned earlier that the basic research in this country is funded essentially by the Federal Government. One fine example to close here.

I work at the Salk Institute where a laboratory around myself is about 30 people. When polio was eradicated after the arrival of the first polio vaccine from Jonas Salk, the Salk Institute was created, with Dr. Salk as its first director, as evidence of the gratitude of the people in this country through the March of Dimes.

The Salk Institute receives no money from patents on the polio vaccine. Neither Dr. Salk nor the March of Dimes ever took any patent on the polio vaccine. We receive nothing out of all of that.

With probably 8 percent of moneys coming from the efforts of our administration as endowment, all of the research of an institution like the Salk Institute, all of it, comes exclusively from the NIH. Any reduc-

tion of that budget means an equivalent reduction immediately of whatever research is going on in an institution like the Salk Institute. The significance of that for the future is exponential.

Thank you very much.

PREPARED STATEMENT

Senator WEICKER. Thank you, Dr. Guillemin. Your statement in its entirety will be inserted in the record.

[The statement follows:]

STATEMENT OF ROGER GUILLEMIN

While I am a physician I have spent the last 30 years of my life working in the laboratory as a physiologist and biologist. I have studied the mechanisms whereby the brain controls all the functions of our endocrine glands. Indeed, we know now that it is a specialized part of the brain that controls the function of the thyroid gland, the adrenal glands in response to stress, the sex glands both in terms of sexual behavior and of reproductive functions. The same region of the brain controls also thirst, hunger, as well as the general growth of the organism leading to our normal height and body size. This work has lead to the discovery of a series of brain hormones controlling all these functions. The molecules are now synthesized by chemistry and are used throughout the world to study and treat several types of disorders ranging from bleeding gastric ulcers, tumors of the pancreas, to fertility problems. For instance, one of these hormones is the cure for a problem in children which is called precocious puberty. While these children were freaks in society until recently, they can now be cured in a few weeks and will resume a normal puberty and life. Another of these molecules is the treatment for these children of very short stature which are called pituitary dwarfs. Senator, the original cost of the first of these hormones when my laboratory isolated it in Houston, TX, in 1969 was weight per weight, five times the cost of the same weight of Moon rock. This same molecule is now produced by industry for a few cents per dose to a patient. It shows right here that both basic research is very expensive and that technology can bring these discoveries for the benefit of the public at some reasonable cost through the efforts of pharmaceutical industry.

The message that I want to bring here is very simple. All basic research in modern medicine and the related biology in the United States and all the advances in medicine that have come from it conducted in universities or research institutes is entirely and exclusively funded by Federal sources. The only exception to that is the research conducted in industry and the small part of university budgets coming from private foundations. What I am saying is that Federal funding for basic research in medicine is not a sort of subsidy for people, the biomedical researchers, who have a source of funding for their research and who just want more money and go to the Federal Government. This is a fundamental difference that must be understood. Federal support for basic research through the NIH or the National Science Foundation [NSF] is really and genuinely the only source of funding for basic research in the medical sciences in the USA.

I am working at the Salk Institute in San Diego in California. The Salk Institute was created and built by the National Foundation March of Dimes for Dr. Jonas Salk to be its first director after the Salk vaccine had eradicated polio not only from this country but practically from the rest of the world. No patents were ever taken by Dr. Salk on his discovery of the polio vaccine. The Salk Institute does not receive royalties for the polio vaccine. With the exception of a small endowment our administration has gathered over the years the total budget of the Salk Institute for all the research going on in the fields of cancer, diabetes, neurosciences, endocrinology, comes exclusively and entirely from Federal sources. Thus it must be clearly understood that if the Federal support for biomedical research disappears or is reduced automatically, then by that percentage number, biomedical research will disappear or be reduced in this country. This is not a matter of having less fancy laboratory facilities, it is a matter of conducting research or not conducting research in the years to come.

Biomedical research in the universities is just as sensitive to Federal funding as that of a research institution like the Salk Institute. University budgets devoted primarily to teaching simply cannot afford the purchase of the new equipment of developing technology, and please be assured that in the community of scientists there is a great willingness to share this expensive type of equipment. This sort of collaboration goes on all the time within institutions and between institutions.

Another point of concern to all of us in medical research, are the attempts which I understand are being made at changing what has been the traditional role of each of the institutes of NIH's in determining and defining what specific areas of research they are interested in supporting--within the constituency of each institute (Cancer, Arthritis and Metabolic Diseases, Eye Institute, Heart and Lung, et cetera). Each insitute has traditionally selected the research, basic or clinical that it will support, through the peer review system. While that system is far from perfect, it is still the best that we know of to appraise the quality of proposals. That sort of nonautocratic, nongovernment ordered or controlled choice for the most judicious spending of public funds must be respected at all costs.

One thing I also want to mention is the overall significance of stability and continuity in funding in reseach. Ups and downs on budget on a yearly or even a 2- or 3-year basis create absolute havoc in reseach programs. Training of young people and laboratory technicians takes years and losing them because of budget instability or reduction is eventually far more expensive than the actual loss of the people involved.

STATEMENT OF THEODORE COOPER, M.D., VICE CHAIRMAN OF THE BOARD, THE UPJOHN CO.

Senator WEICKER. Dr. Cooper.

Dr. COOPER. Thank you, Mr. Chairman.

I, too, would like to submit my remarks as written and just make some highlights, and bring a different perspective this time around to the discussion now that I am in industry.

I think that one of the points that is often overlooked is the stake that industry has in the stability and growth of the National Institutes of Health, and in the Nation's Biomedical Research Program as it is basically funded through public funds.

It has been pointed out many times already this morning the importance of the stability of the university programs. Indeed, I would add to that the Government's own laboratories, the intramural laboratories at NIH. I would point out again that at the moment, the Nation's total effort is a synergistic effort between those two groups and industry.

Dr. Guillemin has pointed out that one of the so-called payoffs from the investment is the ability to produce important therapeutic agents and diagnostic agents at lesser and lesser cost, to take care of more and more people.

The American industry in pharmaceutics is greatly dependent upon the stability of the National Institutes of Health's programs. It has often been suggested in recent years during this debate that industry should replace the reductions that are proposed in research funding by the Government, such as in the President's budget.

I would like to point out that while the industry is increasing its commitment to research, and becoming more research intensive by about 15 percent per year, that it no way could replace the total commitment that is so important to the stability of the programs in academia.

In our own company, for the past 5 years, we have increased our program by 15 percent. We are now investing or reinvesting over 15 percent of our worldwide pharmaceutical sales in research. I would point out in passing that that is 50 percent more than our net profit, and that is a reflection of how important the total research effort is to the competitiveness of this industry, the American industry worldwide, and its ability to bring these exciting new developments to total fruition.

Our company is representative of many of the others. I think Mr. Massinghoff with the PMA has recently reported similar figures for the American industry as a whole, the total investment being about a little over $4 billion at the present time.

We need that access to basic knowledge and basic information produced by the NIH funds. We need the young people to come into our laboratories and complete the development of these leads that they find and that we are able to capitalize on. We need the collaboration with their programs.

We have often been asked, why can't we just subsidize with more collaboration and academic industrial associations have been very much talked about in the last 5 years. They have increased, maybe perhaps doubled, but they, too, have a limit on them. The importance here is that it is mandatory that the academic laboratories not become captives of the industry. They need to maintain their independence, and they need that funding from the traditional sources of endowment, as well as from the National Institutes of Health.

Lou Thomas, a noted and distinguished physician and author, once characterized the National Institutes of Health as one of the greatest social inventions in the history of democracy. We certainly agree with that characterization.

I agree that it is eroding in its potential. We think that our position, worldwide as an industry, is eroding, even though we are still one of the net exporters for American trade. Opportunities lost are not easily regained. Discontinued and interrupted programs can rarely be reestablished.

We, too, would urge you to reject the President's proposal for the National Institutes of Health, and to restore those current levels and stability to the programs, to insure flexibility in their management, as has been described by my colleagues here, and to the extent possible, to foster continued growth during a period of exceptional scientific opportunity.

PREPARED STATEMENT

Thank you very much.

Senator WEICKER. Dr. Cooper, thank you very much.

[The statement follows:]

STATEMENT OF DR. THEODORE COOPER

MY NAME IS DR. THEODORE COOPER, AND I AM VICE CHAIRMAN OF THE BOARD OF DIRECTORS OF THE UPJOHN COMPANY. I WELCOME THE OPPORTUNITY TO COMMENT ON OUR CONCERNS ABOUT THE NATIONAL BIOMEDICAL RESEARCH EFFORT. AS THE RESUME ATTACHED TO MY WRITTEN TESTIMONY SHOWS, I HAVE GIVEN SIMILAR TESTIMONY AS DIRECTOR OF THE NATIONAL HEART, LUNG AND BLOOD INSTITUTE, AS ASSISTANT SECRETARY FOR HEALTH AND AS AN ADMINISTRATOR OF AN ACADEMIC INSTITUTION.

FROM MY CURRENT INDUSTRIAL PERSPECTIVE, I AM CONVINCED MORE THAN EVER THAT THERE MUST BE A STRONG AND STABLE PUBLICLY FUNDED BIOMEDICAL RESEARCH PROGRAM IN THE UNITED STATES, SUPPORTED IN THE MAIN BY INSTITUTIONS SUCH AS THE NATIONAL INSTITUTES OF HEALTH AND THE NATIONAL SCIENCE FOUNDATION AND THE CENTERS FOR DISEASE CONTROL. THE COUNTRY'S INVESTMENT OF PUBLIC FUNDS IN BIOMEDICAL RESEARCH IS AN IRREPLACEABLE FOUNDATION FOR IMPROVEMENTS IN THE PRACTICE OF MEDICINE AND FOR THE GROWTH AND VITALITY OF THE PHARMACEUTICAL INDUSTRY.

PUBLICLY FUNDED RESEARCH GIVES US A RESOURCE FROM WHICH INFORMATION CAN BE DRAWN PROMPTLY AND FROM WHICH NEW LEADS CAN BE TRANSLATED INTO NEW THERAPEUTIC AGENTS.

THIS IS NOT TO SAY THAT INVESTMENT BY THE PHARMACEUTICAL INDUSTRY IN RESEARCH IS INCONSEQUENTIAL. MY OWN COMPANY IS INVESTING INCREASING AMOUNTS OF MONEY IN RESEARCH AND DEVELOPMENT, AND SO ARE THE OTHER RESEARCH-INTENSIVE COMPANIES. ROUGHLY 15 CENTS OF EVERY PHARMACEUTICAL SALES DOLLAR AT THE UPJOHN COMPANY GOES BACK INTO RESEARCH AND DEVELOPMENT. OUR INVESTMENT AS A PERCENT OF SALES HAS BEEN INCREASING AT 15 PERCENT ANNUALLY OVER THE PAST FIVE YEARS.

WE AND OTHERS IN THE INDUSTRY ARE MAKING COMMITMENTS OF THESE PROPORTIONS FOR THREE REASONS. FIRST, STAYING COMPETITIVE REQUIRES INNNOVATION IN PRODUCT DEVELOPMENT. SECOND, WE HAVE BURGEONING SCIENTIFIC OPPORTUNITIES BECAUSE OF THE SO-CALLED REVOLUTION IN BIOLOGY--A REVOLUTION STARTED AND FUELED BY PUBLICLY FUNDED RESEARCH AND GIVEN MOMEMENTUM BY INDUSTRY. THE NEW OPPORTUNITIES HAVE MEANT RESTRUCTURING THE TECHNOLOGY BASE IN MANY COMPANIES. THIRD, THERE IS THE SIMPLE REASON THAT RESEARCH BECOMES MORE EXPENSIVE AS IT BECOMES MORE SOPHISTICATED. THIS LAST FACT IS OF CRUCIAL IMPORTANCE TO THOSE OF YOU IN CONGRESS BECAUSE PUBLICLY SUPPORTED BIOMEDICAL RESEARCH INSTITUTIONS ARE NOT IMMUNE TO THE INCREASED COST OF TODAY'S RESEARCH.

EVEN THOUGH OUR INDUSTRY'S INVESTMENT IN RESEARCH IS LARGE AND GROWING, THAT DOES NOT MEAN IT CAN REPLACE PUBLICLY-FUNDED RESEARCH. WE HAVE BENEFITED FROM THE GREAT EXPANSION OF SCIENTIFIC OPPORTUNITIES IN LARGE PART BECAUSE OF THE PERFORMANCE OF FEDERALLY FUNDED SCIENTIFIC RESEARCH AND CLINICAL INVESTIGATION. THERE IS SIMPLY NO WAY THAT PRIVATE INDUSTRY CAN REPLACE OR EVEN APPROXIMATE THE VALUE AND THE SUBSTANCE OF INFORMATION THAT EMERGES FROM THE PUBLICLY SUPPORTED BIOMEDICAL RESEARCH.

DURING ITS RECENT EXPANSION, THE PHARMACEUTICAL INDUSTRY HAS HIRED A NUMBER OF YOUNG SCIENTISTS WHO WERE TRAINED IN GOVERNMENT AND ACADEMIC LABORATORIES. OBVIOUSLY, THE KEY TO A SUCCESSFUL RESEARCH PROGRAM IS TO HIRE THE BEST PEOPLE YOU CAN FIND. TRAINING THOSE GOOD PEOPLE IS A MAJOR FUNCTION OF PUBLICLY SUPPORTED RESEARCH. CONVERSELY, THE INDUSTRY GIVES MANY OF THESE YOUNG SCIENTISTS A PLACE TO APPLY THEIR TRAINING TO THE DEVELOPMENT OF NEW DRUGS AND INCREASED UNDERSTANDING OF DISEASE PROCESSES.

COMMERCIAL SUCCESS HAS BEEN ANOTHER BYPRODUCT OF THE REMARKABLE AND UNIQUE RELATIONSHIPS OF BIOMEDICAL RESEARCH PROGRAMS IN THIS COUNTRY. DRUGS TO CONTROL HYPERTENSION, PREVENT POLIO, TREAT HODGKIN'S DISEASE AND CONTROL THE COMPLICATIONS OF DIABETES ARE JUST A FEW EXAMPLES OF DRUGS THAT HAVE DRAMATICALLY IMPROVED PEOPLE'S LIVES WHILE AT THE SAME TIME PROVIDING A REASONABLE RATE OF RETURN TO DRUG MANUFACTURERS. I WOULD ALSO ADD THAT WE HAVE SEEN GREAT PROGRESS IN DEVELOPING DRUGS FOR RARE DISEASES. THESE SO-CALLED "ORPHAN DRUGS" ARE ANOTHER EXPRESSION OF THE INTERACTIVE STRENGTH IN OUR BIOMEDICAL RESEARCH SYSTEM.

MUCH HAS BEEN MADE IN RECENT YEARS OF COLLABORATIONS BETWEEN INDUSTRY AND ACADEMIA WHERE THE ACADEMIC INSTITUTION RECEIVES FUNDING FOR WORK TO WHICH THE PRIVATE COMPANY HAS A VARIETY OF RIGHTS. I THINK THE FEARS THAT SUCH ARRANGEMENTS WOULD QUELL ACADEMIC FREEDOM AND SLOW DOWN THE EXCHANGE OF INFORMATION HAVE LARGELY BEEN DISPELLED.

HOWEVER, I WOULD LIKE TO ADD THAT IT'S A MISTAKE TO RELY TOO MUCH ON COMMERCIAL FUNDING FOR ACADEMIC OR GOVERNMENT RESEARCH. UP TO A POINT, COMMERCIAL FUNDING HAS HELPED FACILITATE PRODUCTIVE COLLABORATIONS, BUT MUCH BETTER RESULTS ARE ACHIEVED WHEN A COLLABORATION IS ENTERED INTO TO ANSWER A SCIENTIFIC QUESTION OR MEET A MEDICAL NEED. AN INDEPENDENT FINANCING BASE IS OF GREAT VALUE IN THESE COLLABORATIONS, AND THAT IS WHY ENDOWMENTS AND THE FEDERAL GOVERNMENT SHOULD CONTINUE TO PAY FOR MOST RESEARCH AT ACADEMIC INSTITUTIONS.

IN CLOSING, THEN, AS THE CONGRESS STRUGGLES TO MEET THE GOAL OF A BALANCED FEDERAL BUDGET, I WOULD HOPE THAT IN SETTING THE NATIONAL PRIORITIES THE CONGRESS WILL SEEK TO ENSURE

STABILITY AND A REASONABLE AMOUNT OF GROWTH IN THE NATIONAL BIOMEDICAL RESEARCH EFFORT, PARTICULARLY THROUGH NEW PROGRAMS OF THE NATIONAL INSTITUTES OF HEALTH. OPPORTUNITIES LOST ARE NOT EASILY REGAINED. DISCONTINUED OR INTERRUPTED PROGRAMS ARE NOT EASILY RE-ESTABLISHED. THEREFORE, I BELIEVE ANY PROPOSALS TO ACTUALLY REDUCE FUNDING FOR PUBLICLY SUPPORTED BIOMEDICAL RESEARCH SHOULD BE REJECTED.

THE NATION'S BIOMEDICAL RESEARCH EFFORT TAKES PLACE IN UNIVERSITIES, IN GOVERNMENT LABS AND IN INDUSTRY. THIS TRIAD WORKS TOGETHER IN A SYNERGISTIC WAY. IF ONE PART OF THE SYSTEM IS UNNECCESARILY HAMPERED OR SLOWED DOWN, THE ENTIRE SYSTEM SUFFERS AND IMPORTANT HEALTH NEEDS GO UNMET. LEWIS THOMAS, THE NOTED PHYSICIAN AND AUTHOR, ONCE SAID THAT HE THINKS THE NATIONAL INSTITUTES OF HEALTH ARE ONE THE GREATEST SOCIAL INVENTIONS IN THE HISTORY OF DEMOCRACY. I WHOLEHEARTEDLY AGREE WITH THAT ASSESSMENT. THAT GREAT INSTITUTION IS THE CORNERSTONE OF ALL OUR EFFORTS IN HEALTH, BOTH PUBLIC AND PRIVATE.

THE NATION IS ONLY AS GOOD AS ITS COLLECTIVE HEALTH, OF WHICH BIOMEDICAL RESEARCH REMAINS A CRITICAL DETERMINANT.

THANK YOU. I WOULD BE GLAD TO ANSWER ANY QUESTIONS.

Senator WEICKER. I am going to ask questions of all of you, please any of you respond to them.

The message that you are giving me here today is one that I have heard from the institutes of health themselves. It is one that I have learned through the process of being chairman of this subcommittee.

The question that I have to ask is why the American people don't understand this message, especially in light of the fact that probably no group of individuals has greater credibility to the American people than all of you, and similar colleagues wherever they are located.

Politicians are in low repute. Press people are in low repute. I can go right down the whole checklist, but the scientific profession, I think, has enormous credibility with the American people. Yet, the speculative argument on what we might lose in the way of life in a war against the Soviet Union totally dominates against the actual fact of what we are losing today in terms of life.

I am not here to go ahead and criticize the defense budget, but I am here to say, why this message, which in your varying ways, you delivered here today has not taken hold with the American people, and what really needs to be done to get that message across.

In other words, what needs to be done? What needs to be done to bring this home?

Dr. GUILLEMIN. Sir, if I may say a word here regarding the Endocrine Society, which, as you know, of course, is one of the largest medical societies in this country. Very much like you, we have been concerned by this question, and we, the scientists, have to blame ourselves. We have just not taken enough care in educating the public.

At a council meeting of the society in January, it was decided that we would, in collaboration with our associates, make an official effort, so to speak, to start educating the public through various commitments at our annual meeting, by inviting one of our distinguished representatives from the Senate, and also to start educating, on a nationwide basis, people through TV spots, through television programs, and so on.

I totally agree with you, Senator, it is essentially a question of educating the public about the significance of what we are talking about here.

Senator WEICKER. Your situation is a good example. We absolutely know what the numbers are going to be, nobody disputes that. We know what the numbers are going to be. We know that out of 122 medical schools, only a couple of them are even offering a course in geriatrics, or a degree in geriatrics.

We also know that every time this country has to scramble for a solution to a particular problem, the money that is wasted is just phenomenal, rather than a well-planned approach toward the problem, where we can achieve the results and do it with cost effectiveness.

Nothing comes to mind better than the problem of aging in this country. I find it absolutely ironic that Congress would have passed Gramm-Rudman, and wanted to send a message to the elderly population by saying, we are going to exempt Social Security. In order to achieve that exemption in dollars, they had to cut back on research for

Alzheimer's; they had to cut back on geriatric training; they had to cut back on housing for the elderly.

In effect, what we are saying is, everything is OK, when you get to that age, you can pick up your Social Security check, even though there will be no quality of life at all, you will be OK. How preposterous. How absolutely preposterous.

I can't believe, with the political clout that the aging community has now, that they wouldn't be out there in the forefront of the National Institute of Aging, and making sure that there are adequate professionals to deal with the problem, both as doctors and as researchers, et cetera.

To me it is so dramatic, and the point can be made so well just in this area.

Dr. BUTLER. I think that the American Association of Retired Persons [AARP], the National Council of Senior Citizens, all very important organizations in the field of aging, are so preoccupied with income security for older people, such as Social Security, with the prospect of Medicare cutbacks, and despite the fact that many of us in the research community of aging have approached them, it is somehow not as important to them as these other larger economic issues.

We have reached them. We have talked to them. There are efforts to try to engage their direct help. But it doesn't quite have the punch that Social Security has, and Medicare cutbacks have.

How we can overcome that, I don't easily know. I will assure you, though, that those of us who are in the field of gerontology have been trying desperately to try to get national education on aging in Congress, in the media, to become very much interested in this because the numbers are just spectacular, just staggering. But it is not easy.

Dr. THIER. I was going to expand on what Bob said, in indicating that health is usually not the first concern except when one is sick, other than that, housing, income, and food, and so on, become more important.

That is not an excuse for not doing a better job of educating people, but I would submit that if you look, virtually every newspaper in this country now has a health and/or science section. You cannot pick up a Thursday newspaper without reading what was in the New England Journal last week.

The communications and the magazines are full of discussions of health problems. Sometimes they may be focused on one specific area, and sometimes a little bit alarming. But putting the information out is not, I think, quite as much of a problem, though, I think we will keep trying. There is a problem in communicating with a broad public with multiple interests in abstract concepts where the major advantage of what you do is unseen, and may not be seen for sometime. When it occurs, as with a vaccine or preventive medicine, the key thing that happens is that nothing happens. That is the best we can do. That is a level of abstraction where we have to hope that we can convince the Government and the other people who support this that even if the public

doesn't fully grasp this, this is of great enough moment that one has to move ahead.

In looking at surveys of the public, as the one in the New England Journal in 1984, they didn't want research cut back. They were being pressed on artificial heart and cardiac transplantation, and 84 percent of the public wanted that pursued, when everybody was telling them how much things were costing.

I worry about assumptions about what the public really thinks. I think maybe they think a little bit more about the importance of this when they are threatened, but I also think that this abstract has to be dealt with by those who are responsible physicians.

Senator WEICKER. Dr. Cooper.

Dr. COOPER. I, too, think that the public is very interested in health issues, but they have been educated very successfully in the last 5 or 6 years on a single focus on health policy, and that has been on the cost of health care. So the total focus has been to reduce the cost of health care. If you ask them if they are in favor of the things that they see in increasing amounts on television in immunology, interleuken II, and so on, they are very excited about it, but they can't put into perspective where that fits in the health care cost picture.

As long as we don't make it clear that the total national investment in health costs for research was less than 3 percent of the health care expenditures, they have no frame of reference in which to place that. I don't think that the Congress has really looked at it in that dimension. They have looked at it as a rate of growth of the NIH budget, but they haven't put it in terms of reinvestment as we would have to do in the industry. As I mentioned earlier, we reinvest 15 percent, and as a national program, we can't quite reach 3 percent any more. I think that this is the reflection that the leadership has not put into perspective.

While we are in favor of containing escalating health care cost, one of the best ways to do that over the long run is to reinvest in research, and we haven't made that policy work here in Washington.

Senator WEICKER. I think that you are absolutely right. The figure, actually, we spend $2,000 per person on health care, and $25 on research. How the heck are we ever going to get a handle on that $2,000 figure at that level.

Another question for all of you here, if you would give me some guidance on it. I, and others on the committee, have sort of led this fight on the matter of grants. I think that it was proper, and I still think that it is proper, but I don't want to fall into the trap of focusing on those grants while other things go by the boards, the activities within NIH itself, et cetera, the clinical trials, and whatever have you.

The grants actually do serve a purpose because that is the one thing that is in the public focus, if you will, that they can somehow grasp onto, plus all the grantees, there are enough people to speak up for this program.

Do you feel that there is too much emphasis—I don't plan to let go of it, but do you think that it is also very important, or are we at a

stage where other things should be focused on which might be suffering due to the emphasis on the grant aspect?

Dr. COOPER. Since I am not a grantee at the moment, I would make the observation that if you look at the percentage shift recently, one would get concerned that if all the resources do go into grants alone, that the directors of programs and activities at the National Institutes of Health lose a great deal of flexibility in solving important problems.

The solution to many of the things that have been mentioned earlier were not achieved by grants alone, although they are the foundation—I agree with you that there is a high-priority public perception base on which we go, but if we continue to erode the flexibility of the institute leaders and directors and program directors to do the things that are obvious in managing programs through to their end, eliminating contracts, or training programs, or clinical trials, I think it will further unravel the great fabric that has been woven at the National Institutes of Health for total problem solving.

I, too, believe that the grant program is an essential part of the program, and while fluctuations in the grants themselves should be avoided, I think the rest of that program needs stability. Particularly if there is going to have to be restraint on available resources, the leadership there needs the flexibility to make the best choices for the best research objectives.

Dr. THIER. I would like to echo that a bit. I am not meaning to put the research grants in anything but a primary position, but the logic to me is the same in dealing with this as it is with what we are talking about here today.

If health care is dependent upon research, then research is dependent upon the resources which train the next generation of researchers. To the extent that we short change health care by short changing biomedical research, we will short change biomedical research if we don't put a portion of any increased funding back into the maintenance of the training pool and those institutions in which those individuals are trained.

Anything which undercuts that substrate makes the rest of the position less logical and less likely to sustain.

Dr. BUTLER. I agree, too, with everything that has been said in terms of the importance of the grants. But just to think for a moment about center activities against Alzheimer's disease, and to recall that less than 10 years ago there was only about $700,000 devoted to any kind of research with regard to the brain and aging, and to know today that there are very important leads and opportunities that are being missed.

There are 10 Alzheimer's disease centers which have not been fully funded, so they are limping along, and centers are a way of creating a resource opportunity, populations to study, pathology, basic computer capability, the training of young people, the flourishing of the neurosciences, in no small measure, the consequence of Dr. Guillemin's original contributions, and yet we haven't fleshed out these basic 10 Alzheimer's disease centers.

That is not to say that we should stop there in a problem that constitutes the No. 4 cause of death.

Cancer research should and must have the kind of support that it has, in excess of $1 billion, but it is worth pointing out that that is the No. 3 cause of death. Here we are talking about No. 4 with $53 million, this is minimal given what we see coming like a hard, large Mack truck, right at us, as we just peer a little bit into the next century.

Dr. GUILLEMIN. Of course, I agree with all of this. If research grants are the life and blood of the sort of things I do, we need the people to do all of this research. The disappearance, for instance, of funding for several of the population research centers, of which my laboratory is one, this year, is making us lose completely the possibility of the training and the hiring of postdoctoral fellows. The training of the people, the fellowships for predoctoral and postdoctoral people all over the country is also an absolutely top priority.

Senator WEICKER. That is the bell for our first vote, so I will ask this one last question of the panel, and then I will have to vote, and we will get on with the next panel.

Forget compassion, forget science—I am very serious in this question—looking at it from a budgetary point of view, at the cost, do you consider these cuts to be fiscally irresponsible as to what they will create in the way of additional demands on the health budget?

Dr. COOPER. Yes; I think, clearly, if one looks downstream from the current proposal, what this will do to the institutions with which we deal will be devastating. It will speak also to the need to dismantle programs in which there had been already important investments made, and in which the payoff is soon to be seen. What you will see is the worst kind of fiscal irresponsibility because you have in your grasp the ability to get the return, and you will cut it off arbitrarily by some formula, without any selection or selectivity. It is quite clearly poor fiscal policy.

Dr. GUILLEMIN. I could not agree more with what Dr. Cooper said. Automatic cutting does not make sense. Fiscally, I think that it is totally irresponsible.

Dr. BUTLER. It has got to be especially devastating to the newest of the institutes, aside from the Arthritis Institute, particularly dealing, as it must, with those huge numbers coming down the track. The National Institute on Aging is 2 percent of the entire NIH budget despite those heavy health costs, and it was never adequately capitalized to begin with. So it is devastating in terms of training opportunities, center development, any efforts to reach clinical trials, for example, at the Heart Institute with regard to systolic hypertension.

So it is altogether a particularly destructive move budgetarily to a new and vital institute.

Senator WEICKER. Dr. Thier.

Dr. THIER. I can't improve on those comments.

Senator WEICKER. Gentlemen, I thank you for the time that you have given us, and your thoughts. All statements will be included in their en-

tirety in the record. Any questions of any members of the committee will be submitted to you, hopefully for a response.

Dr. Cooper, did you bring some of that hair growing stuff?

[General laughter.]

Dr. COOPER. I will give you a private consultation.

[General laughter.]

Senator WEICKER. The subcommittee will stand in recess for 10 minutes while I go to the floor and vote. Thank you.

[A brief recess was taken.]

Senator WEICKER. The subcommittee will come to order.

Our second panel consists of Dr. Kenneth Shine, president-elect of the American Heart Association; Dr. John Durant, president, the Fox Chase Cancer Center; Dr. Herbert Pardes, chairman of the Department of Psychiatry at Columbia University; and Dr. George Palade, winner of the Nobel Prize for Medicine and the Presidential Medal for Science.

Dr. Pardes, why don't we start with you. All the same ground rules as before.

Gentlemen, I want to apologize ahead of time that Senator Hatfield will be replacing me in the chair. I wish I could listen to all of the testimony. Indeed, you are even getting a higher ranking official in the sense that the chairman of the full committee will be here to listen to that testimony.

Dr. Pardes.

STATEMENT OF DR. HERBERT PARDES, CHAIRMAN, DEPARTMENT OF PSYCHIATRY, COLUMBIA UNIVERSITY

Dr. PARDES. Senator Weicker, it is a pleasure to testify before you. I personally want to tell you how much we appreciate your leadership in this effort.

I will submit my formal statement for the record.

The administration's budget for the Alcohol, Drug Abuse, and Mental Health Administration [ADAMHA] betrays a callous disregard for the over 30 million people suffering from alcoholism, drug abuse, schizophrenia, and other mental illness. This is particularly ironic today for research in this field has never been more promising.

The proposal begins what I think is the dismantling of the already rather modest research effort we have to conquer these diseases. For every patient treated for cancer, more than $300 is spent on research and we applaud that effort. We are dismayed, however, that for schizophrenia, the analogous figure is only $7.

Government money is critical in the support of research for mental illness and substance abuse. Ninety percent of the research on mental illness comes from the public sector, contrasted to some 58 percent for research on other health areas. Because of the stigma, the private world also gives little for mental illness research.

If there are some 5,000 researchers working on star wars today, and I understand that this is projected to go to something like 19,000, the number of substantial researchers working on schizophrenia probably

numbers more than 100 to 200 in this country. These figures were appalling enough in past years, today in the face of a research explosion in the sciences related to mental illness and substance abuse, they represent nonsensical policy economically and a national disgrace from the human perspective.

If we spent an estimated $185 billion, according to an IOM report, in 1980, $213 billion in 1983 on expenses for these disorders and the services for them, given that research offers exciting possibilities for finding answers which would lower that cost, why nickel and dime that effort and reduce it, as the administration suggests, by reducing the budget to $348 million for research and research training in fiscal year 1987.

We have had examples already of savings from research. You asked the question earlier, Senator Weicker. Lithium, its introduction in this country, has saved something in the neighborhood of $6.5 to $7 billion in the last 10 to 15 years. But there are many other research developments.

The scientific world has recognized that neurobiology and brain research, research related to psychiatric illness is particularly exciting and promising. We have confirmed that heredity is a major contributing cause of alcoholism. We have demonstrated that the anticonvulsant tegretol is effective in treating and preventing episodes of manic depressive disease. This will complement the use of lithium because there are some people who don't respond to lithium, but will respond to tegretol.

We have identified and studied the consequences of drug use, including the effects of drugs on fetal development, motivation, and emotion. We have identified some of the subcellular biochemical changes in the nervous system of animals during learning and the formation of memory. If we can get a handle on learning and memory, we can do considerable amounts for people with learning disabilities, for people who are institutionalized because of deterioration of memory.

We have discovered the strong link between alcoholism and harm to the fetus. We have discovered the key role of neuronal receptors in the communication system of the brain. We have provided new evidence that imaging technology can help us understand some of the brain disorders.

We have demonstrated that the behavioral psychological concomitants of AIDS may be due to the invasion of neurons by the AIDS virus. There are countless other examples of new knowledge and new approaches that enable us to mount a reinvigorated attack on these illnesses, but not with the administration's budget.

That budget would introduce a new stabilization policy based on the total number of grants supported by each agency. For ADAMHA, the OMB number is 1,400 total research project grants, 930 of which are by definition reserved for continuation support to present investigators.

The resultant adverse impact of this type of stabilization is a dramatic reduction of almost 20 percent in the number of new and competing research projects, from 550 to only 448. Worse, instead of establishing a

stable and predictable level of competition among scientists for research support, sciences, under this proposal, will once again become faced with a wild fluctuation in the level of grant availability from year to year.

Adoption of the President's budget would specifically reduce the number of National Institute of Mental Health [NIMH] new and competing regular research grants to 257, 62 fewer than Congress authorized in 1986. It will allow the National Institute on Alcohol Abuse and Alcoholism [NIAAA] to fund only 74 new and competing grants, 26 fewer than the level appropriated by Congress in fiscal year 1985 and 1986. It will drop the number of new and competing grants at the National Institute on Drug Abuse [NIDA] from 131 to 117; prohibit the award of any new and competing grants for NIMH research centers dedicated to basic and clinical studies of mental illness. I find this an almost unbelievable recommendation even for this administration.

It will reduce the total number of NIMH research trainees to 751, a reduction of nearly 50 percent over 6 years. It will slash by one-third the number of research career development awards and small grants which were authorized by Congress in 1986. These are the mechanisms to complement the research grants which bring young investigators into the field and sustain them.

Mr. Chairman, the Ad Hoc Group for Medical Research Funding, this year, is joining with us in urging the Congress to appropriate a major infusion of new research dollars into areas within the ADAMHA purview. I intend to offer that statement also, if it is acceptable with you, for the record.

They stated, "This increase is necessary to achieve catch-up growth in funding of mental health and addicted research, and restore ADAMHA's purchasing power for research and research training to the constant dollar level of 1974."

A coalition of 41 organizations primarily concerned with the adequacy of Federal funding of the ADAMHA field has also endorsed these funding recommendations. Specifically, the alternative budget we champion provides the necessary expansion in the level of competing and noncompeting research project grants with full funding at study section recommended levels; critical growth in research centers, including sufficient funding for competing renewals; research scientist development awards,. and funds sufficient to raise the number of research trainees to that recommended by the National Academy of Sciences. It will also help us to get needed renovation of outmoded research labs and equipment, and also to supply necessary funds for the intramural program, to provide for the replacement of obsolete equipment, and to regain position.

This proposal does not seek to play a numbers game and establish another arbitrary formula in place of that proposed by the President. Rather the proposal is based on the present scientific excitement in the field and the importance of the research that can be done. It is derived from the scientific opportunities and recommendations of the Institute of Medicine report.

I will add, the specific statements are in the full statement that I will submit for the record.

What lesson is the administration, with its budget proposals, teaching to those suffering from substance abuse disorders?

What lesson is taught those young doctors and others considering a career in research into these illnesses?

For the former, it is a reaffirmation to the stigma attached to mental illness or addictive disorders. For the latter, it is a confirmation that the Nation's research commitment does not lie in this field, and that entering it is folly. A vicious cycle of diminished financial resources leading to diminished interest and involvement in research is created, resulting in tremendous potential loss to society as a whole.

If the Nation fails to invest wisely in efforts to reduce the costs of mental illness and addictive disorders, we all will continue to pay the price in increased hospital care, increased secondary illness, lost productivity, and, ultimately, lost lives.

PREPARED STATEMENT

We are confident, Mr. Chairman, that enhanced funding can yield dividends in advancing scientific knowledge, and we stand ready to work with you in this endeavor.

Thank you.

[The statement follows:]

STATEMENT OF DR. HERBERT PARDES

Mr. Chairman, I am Herbert Pardes, M.D., Chairman of the Council of Research of the American Psychiatric Association, a medical specialty society representing over 32,000 psychiatrists nationwide, on whose behalf I appear today. I am also Chairman of the Department of Psychiatry at Columbia University and Director of the New York State Psychiatric Institute. I am pleased to appear before the Subcommittee today to share with you the APA's reaction to the President's FY '87 wholly inadequate and inappropriate budget proposals for research programs supported by the Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA) and to present you with a scientifically-justifiable and critically important viable alternative.

The President's proposal for ADAMHA research and research training totals $348 million in FY '87, a reduction from the comparable level of $366 million in FY '86 (prior to the Gramm-Rudman triggered sequestration of funds). Of this reduced amount, an additional $9 million, in AIDS-related research dollars, is proposed to be taken away and transfered to the office of the Assistant Secretary for Health. This $348 million level -- without regard to the further effective reduction of $9 million -- is actually well below the "no-growth" or "current services" benchmark level of $406 million (i.e. the amount that is needed to continue the same level of activity in FY '87 as in FY '86.) The President's recommendation must also be weighed against the professional judgment recommendation of $465 million by the prestigious Institute of Medicine of the National Academy of Sciences. This represents in the judgement of the IOM the necessary second year-infusion of funds to accomodate the goal of a dramatic 5-year growth rate in ADAMHA-supported research. The IOM makes its recommendations cognizant of the fact that over 90% of funding for mental illness research emanates from the public sector.

As you know, the cornerstone of the President's budget for both NIH and ADAMHA research is a new stabilization policy based on the total numbers of grants supported by each agency. For ADAMHA the OMB number is 1400 total research project grants, 930 of which are by definition reserved for continuation support to present investigators. The resultant adverse impact of this type of stabilization is a dramatic reduction in the number of new and competing research projects from 550 to only 448. By adopting a new

definition of "stablization" of research grant support, the OMB has imposed a significant restriction upon the availability of new and competing awards, contrary to both the historical definition of new and competing awards and to the opinion of key science advisors. Worse, instead of establishing a stable and predictable level of competition among scientists for research support, scientists under this proposal once again become faced with a wild fluctuation in the level of grant availability from year to year. The chance of funding will depend more upon when their application is considered, than on the quality and merit of the proposal. This arbritrary formula also imposes equally arbitrary and unnatural patterns of research support because it emphasizes a fixed number of grants at the expense of other important activities including research centers.

A sampling of ADAMHA research activities shows that adoption of the President's budget would specifically:

- Allow NIAAA to fund only 74 new and competing grants, 26 fewer than the level appropriated by Congress in FY 1985 and 1986; and require 16% cuts in the average costs of the new and competing awards that can be funded;
- Reduce the number of NIMH new and competing regular research grants to 257, 62 fewer than Congress authorized in 1986;
- Drop the number of new and competing grants at NIDA from 131 to 117;
- Prohibit the award of any new and competing grants for NIMH research centers dedicated to basic research and clinical studies of childhood disorders, the mental health of the elderly, major psychoses, the genetic bases of mental disorders, and prevention; six highly productive centers currently supported by NIMH funds would not be renewed.
- Reduce the total number of NIMH research trainees to 751 (a reduction of nearly 50% over six years); further reduce the already insufficient number of research trainees at NIAAA and NIDA to 63 and 68, respectively.
- Slash by one-third the number of Research Career Development Awards and small grants which were authorized by Congress in 1986. These programs are essential in attracting and maintaining a cadre of highly talented young researchers in the field.

I want to take a moment to emphasize a critical proposed budget shortfall in the Research Centers mechanism, where six highly productive centers eligible for renewal funding, are zeroed from the President's budget. Teams

of skilled researchers supported under NIMH center authority are developing critical masses of knowledge around the origins of severe mental disorders of such populations as children and the elderly. We urge your Subcommittee to act prudently by restoring necessary continuation authority for these research centers. These proposed reductions are damaging in themselves, but even more so when held up to the light of the present burgeoning opportunities for improved, cost effective treatments.

The ADAMHA research mission covers a large and diverse range of people with an overall prevalence of mental and addictive disorders for all age groups in the United States in the range of 15 to 22.5 percent. Thus ADAMHA supported-research is of direct relevance to 30-45 million Americans, including of over 2 million children with serious mental disorders and at least 10 percent of our citizens who are over 65 years of age. For example and by comparison, only 5 to 6 million Americans have been treated for cancer at some time and another 35 million have been told by a physician that they have a cardiovascular disease. For every patient treated for cancer, more than $300 is spent on research; for schizophrenia the sum is $7. Overall, yearly expenses for mental and addictive disorders total an estimated $185 billion in 1980 (IOM Report). By 1983 that number had risen to $218 billion.

We feel that an explosion of research on the brain, one of the last frontiers of medical science, will offer eventual cures for some of today's most feared disorders. The recent track record justifies our confidence. In the conduct of research into mental illness, alcoholism and drug abuse, ADAMHA-supported research has already:

- Confirmed that heredity is a major contributing cause of alcoholism in a substantial proportion of cases and provided clues to the physiological and molecular basis of the genetic predisposition to alcoholism.

- Demonstrated that the anti-convulsant Tegretol is effective in treating and preventing episodes of manic depressive illness, important both because it is particularly effective in people unable to tolerate or otherwise unable to utilize lithium and because it has opened up the potential similarity of psychobiological mechanisms surrounding manic depression and seizure disorders. Earlier estimates of the cost savings as the result of the introduction of lithium (approximately $6.5 billion

in the past decade) can be expected to increase 20-50% with the addition of this drug to the arsenal of psychotropic medications.

- Identified and studied the consequences of drug use, including the effects of drugs on fetal development, motivation and emotion, personality and cognitive abilities, and performance, as well as the consequences of cessation of chronic drug use.

- Identified the precise, sub-cellular biochemical changes in the nervous systems of animals during learning and the formation of memory, both major components of all complex behavior. The significance of this discovery earned the Lasker Award and other major scientific prizes.

- Uncovered the strong link between alcohol and harm to the human fetus; and further found that even if a mother receives a nutritionally adequate diet, alcohol interferes with the transport of nutrients across the placenta, causing malnutrition in the fetus.

- Demonstrated that the use of alcohol damages the central nervous system at an earlier point in its use and that the damage is not as localized as previously had been thought.

- Developed behavioral interventions that reduce the incidence of delinquency among high-risk children and youth;

- Produced evidence that alcohol abuse may exacerbate the neurochemical events associated with violent behavior.

- Developed effective school-based programs for preventing drug experimentation by adolescents, as well as community-based programs for the prevention of drug abuse by adolescents and their families.

- Discovered the key role of neuronal "receptors" — the parts of nerve cells that receive chemical messages from adjoining cells — and developed techniques for mapping the location of these receptors throughout the central nervous system.

- Provided new evidence, through use of sophisticated imaging techniques, of structural brain abnormalities, especially decreased frontal lobe size, in schizophrenic patients; found that early cognitive deficits may be a basis for identifying children at high risk of schizophrenia.

- Demonstrated that many amphetamine drugs and their derivatives produce long-term, possibly irreversible, changes in brain neurotransmitters, and found and defined the toxic effects of inhalent-type drugs on the auditory system.

- Demonstrated that the behavioral and psychological concomitants of AIDS may be due to invasion of neurons by the AIDS virus.

- Demonstrated preliminary links between the HLA antigen and auto-immune antibodies for the development of severe tardive dyskinesia, a

disfiguring movement disorder which may be seen as a schizophrenia.

- Developed new methods for separating brain proteins, allowing investigators to detect patterns of protein genetic variations, much like fingerprinting, that correlates well with susceptibility to alcohol dependence.

Mr. Chairman, the Ad Hoc Group for Medical Research Funding (on which APA serves as an executive committee member) this year is joining with us in urging the Congress to appropriate a major infusion of new research dollars into areas within the ADAMHA purview. The group's recommendation -- despite its membership keyed to NIH -- for NIH-sponsored -- as contrasted to ADAMHA sponsored -- research documents the ADAMHA shortfall and critical funding need. They state that, "this increase is necessary to achieve catch-up growth in funding of mental health and addictive research . . . and restores ADAMHA purchasing power for research and research training to the constant dollar level of 1974." When looked at from this necessary historical perspective, the FY '87 appropriations recommendations of the American Psychiatric Association, the Ad Hoc Group and other coalitions are, to my mind, eminently reasonable and both politically and scientifically justifiable. I must add that a coalition of over 41 organizations primarily concerned with the adequacy of federal funding in the ADM field has also endorsed these funding recommendations and I ask your permission to insert the coalition statement into the hearing record.

Specifically, the alternative budget we are all championing provides for:

- necessary expansion in the level of competing and non-competing research project grants with full funding at study section-recommended levels.
- critical growth in Research Centers (including sufficient funding for competing renewals); Research Scientist Development Awards (which particularly focus on establishing a pool of talented young investigators); and funds sufficient to raise the number of research trainees to that recommended by the National Academy of Sciences.
- needed renovation of outmoded research laboratories and equipment.
- necessary funds for the Intramural programs to provide for replacement of obsolete equipment and to regain lost positions.

This proposal recognizes the extraordinary contributions of ADAMHA-supported research and would hasten the growth and refinement of new knowledge and clinical applications.

This proposal does not seek to play a "numbers game" and establish another arbitrary formula in place of that proposed by the President. Rather, this proposal is based on the present scientific excitement in the field and the importance of the research that can be done. It is derived from the scientific opportunities and recommendations of the IOM report. Specifically, it would:

- Permit support of 425 new and competing NIMH regular research grants, 168 more than the number which would be supported under the President's proposal;
- Permit NIAAA to award 116 new and competing investigator-initiated project grants at IRG-recommended levels; an increase of 16 percent over the number awarded in FY 1986;
- Allow NIDA to add 16 new and competing grants above the FY 1986 level of 100 awarded, including the funding for 3 major grants to support large clinical and treatment research projects;
- Enhance dramatically NIMH's ability to support university-based Research Centers: continuation levels would be restored to the levels approved by the NAMH Council; the six competing renewals otherwise lost in FY 1987 would be continued; and three new Centers (focusing on schizophrenia, childhood disorders; and mental health of the elderly) would be funded, as would two Centers investigating AIDS-related mental health issues;
- Augment the Research Scientist Development Award program -- with special emphasis on talented, young clinical researchers, to ensure the future availability of well-trained personnel;
- Increase the number of research trainees supported by NIMH from 751 permissible under the President's budget to 1200, and expand the number of research trainees and NIDA and NIAAA to 100 and 80 respectively -- a significant step toward the 1500 trainees recommended by IOM;
- Ensure adequate personnel and equipment for the Intramural Research Programs of all three ADAMHA Institutes.

What lesson is the Administration with its budget proposals teaching to those suffering from mental or substance abuse disorders? What lesson is taught those young physicians and others considering a career in research into these illnesses? For the former, it is a reaffirmation of the stigma attached to mental illness or addictive disorders. For the latter, it is a confirmation that the Nation's research commitment does not lie in this field, and that entering it is folly. A vicious cycle of diminished financial resources leading to diminished interest and involvement in research is

created, resulting in tremendous potential loss to society as a whole.

If the Nation fails to invest wisely in efforts to reduce the costs of mental illness and addictive disorders, we all will continue to pay the price in increased hospital care, increased secondary illness, lost productivity and, ultimately, lost lives.

We are confident, Mr. Chairman, that enhanced funding can yield dividends in advancing scientific knowledge, and we stand ready to work with you in this endeavor.

Senator HATFIELD [presiding]. Thank you very much, Dr. Pardes.

Senator SPECTER. Mr. Chairman, I wonder if I might——

Senator HATFIELD. Yes; just one moment.

Dr. Pardes, I want to especially welcome you to the subcommittee today, and to thank you for your very eloquent testimony. You have always been most articulate on behalf of your area of medicine and research.

You have made a comment about the President's budget. I think that it is pretty clear by now that the President's budget was DBA, dead before arrival, and not on arrival, and that was affirmed by, first of all, this subcommittee under the chairmanship of Senator Weicker, from the first hearing that we held, that we were not going to measure our product, or what we wanted to end up with as our product, by the President's budget. Then, the Budget Committee itself put it to a test, and got only, I think, five votes for it. So I think that it is pretty clear that the Congress is not moving in that direction.

I wish I could be definitive at this time to you, except to say that I know that under the leadership of the Appropriations Committee, in general, the subcommittee in particular, there is a very strong commitment to medical research which far exceeds that which are the levels indicated by the President's budget.

The Senator from Pennsylvania.

Senator SPECTER. Thank you, Mr. Chairman.

I just wanted to say a word or two of introduction about Dr. Durant, who is the next witness.

Dr. Durant is the president of the American Society of Clinical Oncology, and president of the Fox Chase Cancer Center in Philadelphia, a very distinguished clinician and physician. I wanted to make those very brief words of introduction for him. As usual, we introduce those who do not need introductions, but as a longstanding friend, I wanted to be here to say that.

I have reviewed his statement, and it is an excellent one. I regret that other commitments prevent my staying.

I would associate myself with your remarks, Mr. Chairman, about my own commitment to medical research, evidenced by my votes in support. I think that this subcommittee will lead the way in providing the

kind of assistance necessary and appropriate for the very important research work in this country in the medical field.

Thank you, Mr. Chairman.

Senator HATFIELD. Thank you, Senator Specter, for your comments and the introduction of Dr. Durant.

We are happy now to hear from you, Dr. Durant. Welcome to the subcommittee.

STATEMENT OF JOHN R. DURANT, M.D., PRESIDENT, THE FOX CHASE CANCER CENTER

Dr. DURANT. Thank you very much, Senator Hatfield.

I would like to reiterate a theme that you have heard this morning again and again, and that is that the opportunities were never greater. Fifteen percent of the people who work in my basic research operation are members of the National Academy of Sciences, so they are not trivial in their achievements, and there was never more excitement in our laboratories about the potential for doing something important about the problem of cancer.

In addition, what Senator Specter didn't tell you is that it is very important to me personally. My wife happens to have the disease. My sister has the disease. My mother and father-in-law also both have the disease. So I have a personal investment, which many Americans have, in seeing something important done about this problem.

If you were running a business and you had the opportunity to make $13 on every $1 you put into the business, I think that you would probably take it. That is what we think the fiscal opportunities are in fundamental biomedical research in this country. I think that it is penny-wise and pound-foolish to follow the principles of the President's budget.

There are a number of consequences that I would like to stress about some of the things that are happening. First of all, if this comes to be, at least at the National Cancer Institute, the percentage of grants to be funded would fall to about 27 percent, well below what is believed to be the optimal level of funding for new and competing research grants, a very important fundamental basis for our research effort.

Second, I am very concerned about the facilities in our country. Sam Thier testified in the last session about the report to Dr. Keyworth that was delivered last year at the request of the President concerning the state of facilities and indirect costs in our country.

The need for operating budgets, I think, is measured in the tens of millions of dollars and the need for improving and renovating our facilities may be in the hundreds of millions of dollars. Recently, Dr. Armand Hammer and the American Cancer Society funded a study of just what would be needed for cancer research and for all the research establishment, and they found that universities and research institutes, such as the one I represent, were going to raise new funds of their own of about 56 percent, but they needed 44 percent from the Federal Government, and that represented $350 million just for cancer research facilities over the next 4 years.

In addition, the Keyworth report suggested that indirect cost reimbursement related to amortization of buildings and equipment were unduly unrealistic. Buildings are amortized over 50 years at present, and they recommended 20. Equipment is amortized over 15 years, and they recommended 5 to 10. This would drive up indirect costs, not down as is currently being recommended.

Another important area that has been mentioned before is centers. We are currently operating at my center, before Gramm-Rudman, at 88 percent of recommended levels, that is a similar budget reduction to most of the cancer centers in the United States. Congress has previously suggested that these should be funded at 100 percent. If the budget cuts occur, of course, they may be reduced still further.

Once again, I would like to say, I think the opportunities were never greater, but we are about, if something is not done, to waste these opportunities in what I consider to be foolish budget reductions.

PREPARED STATEMENT

I thank you for the opportunity to speak to this issue.

[The statement follows:]

STATEMENT OF JOHN R. DURANT

I am John R. Durant, M.D. I am president of the Fox Chase Cancer Center located in northeast Philadelphia. We are, with the University of Pennsylvania, 1 of the 20 comprehensive cancer centers designated by the National Cancer Institute. We have an annual budget of about $47 million and expend $18 million annually on cancer research. Of this $18 million, about $14 million is provided by peer reviewed applications, most from the National Institutes of Health. I am also president of the American Society of Clinical Oncology, an association of more than 6,000 clinicians who care for most of the Nation's cancer patients and which represents most of the academic clinical oncologists in the United States. I have recently been appointed by President Reagan to the National Cancer Advisory Board, the 18 person policy advisory group which serves the Director of the National Cancer Institute. I am past president of the American Radium Society, the oldest clinical cancer research organization in the country, and of the Association of American Cancer Institutes which represents most of the academic cancer centers in the United States. Finally, I am treasurer of the National Coalition for Cancer Research which represents most of the professionals in the United States who do cancer research. Therefore, I feel particularly qualified to discuss the problem of funding for cancer research.

Senator, you are familiar with the highly publicized effort, which you supported, to fund 6,100 new research grants this year. I support this effort; however, its effectivensss is being seriously eroded by the Gramm-Rudman-Hollings Act which, if permitted to persist, will eventually remove $13 of benefit to the economy for each $1 of savings to the budget. This is severe enough by itself, but is trivial compared to the long-term effects of the relatively stable budget in dollars which has occurred for the National Cancer Institute over the past decade. No real increases in dollars and, therefore, real decreases of significant amounts have affected the budget for centers, training, construction, the intramural programs, and clinical trials. Centers are now operating at 88 percent of recommended levels. Training of new academicians is more essential than ever. Clinical trials, the mechanism by which bench research is translated to public benefit, are suffering badly. Because of severe cutbacks in funds, the National Cancer Institute is going to have to eliminate seven groups this year, a severe dismantling of the system. The problems of the intramural program are well known.

The most important problems, however, are construction, renovation, and equipment. Two recent studies demonstrate the dimensions of the problem. The ACS-Armand

Hammer study indicated that just for cancer research, the academic centers of this country would need $1.5 billion to modernize their facilities by 1990. They anticipated that they could raise 56 percent of this from their own sources, but 44 percent ($360 million) would have to come from Federal sources. The Keyworth report to the President, delivered in December 1985, stated that current assumptions regarding depreciation in the indirect cost reimbursement formula were unduly stringent. It was recommended that amortization for buildings be over 20, not the current 50 years, and that for equipment be 5–10 years instead of the present 15. These two reports come at a time when $1 million is all there is in the budget for the National Cancer Institute for new construction and when the Office of Management and Budget wants to reduce indirect costs, not increase them as President Reagan's last science advisor recommended.

Senator, I live in the Northeast where the general infrastructure has been allowed to deteriorate through deferred maintenance. Our roads are a series of pot holes traversing cities whose sewage and water systems leak and which contain hundreds and thousands of acres of abandoned buildings. We must not allow our biomedical scientific infrastructure to suffer the same fate. The budget for this purpose is the people's defense budget against disease. They are more afraid of cancer than any other disease. The infrastructure which supports the research to defend against this disease is under penny-wise and pound-foolish attack.

I urge you, therefore to:

One, oppose changes designed to reduce indirect cost reimbursement.

Two, support generous funding for the National Institutes of Health and the National Cancer Institute—this year's appropriated budget of $1.2 plus billion for the National Cancer Institute would be a good start.

Three, support funding, as the Congress has done in the past, at 100 percent of recommended levels for centers.

Four, maintain research training.

Five, restore cuts in the intramural budget.

Senator, our Nation's defense budget against disease is every bit as important as its budget against nuclear and conventional war. We cannot negotiate either from weakness. Neither can we expect research to be done when insufficient numbers of new scientists are being trained to work in increasingly outmoded facilities equipped with aging and outdated equipment.

I urge the prompt attention of the Congress to these urgent and important matters.

Senator HATFIELD. Thank you, Dr. Durant.

You know, Dr. Durant, you touch on a very deep concern of mine, which is to look beyond the dollars involved and whether we are funding at so many dollars or other dollar levels, whatever, because when we are aware that over 60 percent of the teachers in secondary education today in America are temporarily certified in order to provide some kind of a teacher role in those classrooms—temporarily certified because they are not truly qualified to teach those subjects from an academic background or experience or education—it really tells us what is happening to the foundation, which ultimately will be manifest in all fields of research in the scientific medical field, because if we are not getting those secondary programs bolstered in quality to stimulate, to bring students' interest to a peak, to follow through into the higher educational experience, we are really losing the very basis of the whole enterprise of research. That concerns me.

Another thing that concerns me is that no matter how many dollars we may fund at this particular program in medical research, look at the growing competition for that limited personnel, scientists—Herb has heard me talk about this frequently, and he is probably saying, here I go again. I just feel that it has to be repeated every chance I have.

There are 5,000 research scientists and engineers this year in SDI. The funding level requested by the administration will boost that in 1987 to 18,600 scientists and engineers in SDI.

The issue is that even with the higher dollars, you are going to find yourselves competing for the dollars because researchers follow the dollars, let's face it, and three out of four Federal dollars for research are going now into military research.

I am not saying that there is a transfer of science and knowledge, and all that, that comes out of even military research. But I am saying that we have to look more precisely at some of the infrastructures, as well as the dollars. It is not either/or, and that concerns me.

You have touched on that very well here in your testimony, about some of that support auxiliary personnel problem. These dollars are more than just budgetary dollars, they translate into people priorities. Does it sound familiar?

Dr. PARDES. I don't find any objection to your saying it a number of times. I would just like to get you as many cameras as possible so that you could say it to as many people as possible.

Senator HATFIELD. Just wait until we get television in the Senate, and then I will have a blue shirt on, and I will say it right on the floor of the Senate.

STATEMENT OF KENNETH SHINE, M.D., PRESIDENT-ELECT, AMERICAN HEART ASSOCIATION

Senator HATFIELD. Dr. Shine, we are happy to welcome you as well here today. Your full résumé and who's who will be placed in the record. I want to now turn to you to let you take advantage of the time that we are working under today to make your statement.

Dr. SHINE. I am Kenneth Shine, dean-designate of the UCLA School of Medicine. I would want to echo, in that capacity, Dr. Butler's comments this morning. We were among the real pioneers in geriatric education and training in the United States, and we are scrambling desperately to maintain those programs as Dr. Butler described.

I am also president-elect of the American Heart Association; it is wearing that hat particularly that I appear before you today.

We are very pleased that these hearings have been called because we believe that the public needs to become aware of this administration's budget proposals and their management policies as they impact upon biomedical research.

While the American Heart Association [AHA] continues to dedicate an increasing amount of its budgetary resources to plant seeds among young people to undertake careers in cardiovascular research, we are hopeful that the National Heart, Lung, and Blood Institute [NHLBI] will be able to continue to take advantage of current and future research opportunities in the field.

We are becoming increasingly concerned that decisions made by Federal officials for fiscal reasons in the present, may have detrimental long term impact on the ability of the institute to do so.

This morning, we were talking about fiscal implications. The economic cost of cardiovascular disease in this country is about $102 billion. Since 1964, over a 20-year period, there has been a 39-percent decrease in the mortality and morbidity in cardiovascular disease. Translate that into dollars, and we are talking about a cost that would have been $68 billion higher, that is somewhere in the range of $170 billion, and that is more than my lunch money, Mr. Chairman.

In addition to the Gramm-Rudman funding reductions that have already had a severe impact on NHLBI's programs, we are very concerned with management changes and additional funding reductions that appear on the horizon.

The President's 1987 budget proposals would require deep reductions in the programs of the Heart, Lung, and Blood Institute when research momentum, as already has been described, should not be slowed. The budget includes only $785 million, an overall reduction of 4.5 percent from fiscal year 1986, and below the adjusted appropriated level of $822 million.

The programmatic impact of the proposals on the Heart, Lung, and Blood Institute will be devastating. My written statement highlights the impact on each of the program mechanisms, but I would like to highlight one particular program area, namely, cholesterol research and education.

This is a prime example of where a voluntary health agency, such as the heart association, and the NHLBI work in a cooperative manner, both for prevention and treatment. It is noteworthy that the 1985 Nobel Prize went to Goldstein and Brown, who were supported by the heart association and the NHLBI, and whose research provides many of the clues which can be translated into decreasing death and disability from heart disease.

In the area of cholesterol research, over $4 million of grants in the NHLBI approved in 1986 will not be funded as a result of budget reduction. One important workshop on severe hypercholesterolemia has been canceled, another on the impact of dietary cholesterol and plasma lippoproteins is in jeopardy. There are a number of planned areas of investigation and education which will not be carried out because of a shortage of funds.

We have had to reduce the total number of publications with regard to cholesterol, and to reduce the number of spokespersons who can talk about the national cholesterol education project at conferences and meetings because of reduced travel.

The institute will have to reduce in scope some activities that are already underway, and it will have to decrease its activities in broadcast and print in carrying the program's message to the public.

The American Heart Association believes that the institute's efforts in cholesterol research and education should not be sidetracked or slowed at this time. We spent a substantial amount of money on the lipid research trials, they clearly demonstrated the efficacy of reducing cholesterol, and any reduction in funding which does not take advantage of this clearly does not allow a payoff on a previous investment.

The American Heart Association believes that the budgets for the national institutes are inadequate, and we will be appearing later this month to discuss this to a greater extent. At the same time, we would also like to highlight some of our concerns regarding the increasing involvement of the Office of Management and Budget [OMB] in the management activities of the institutes.

As we understand the situation, as of August 1985, the OMB instituted a new mechanism for apportioning funds to the institutes which, in turn, required the Office of the Director of the NIH to adjust its allotment procedure to the individual institutes. Prior to August 1985, OMB apportioned funds to the institute by total, and then the Director of the NIH allotted funds to the individual institutes with only two categories earmarked, SBIR and consulting services.

Allocation among programs of the remaining and largest parts of the institutes' budget were left to the individual institutes. Now the institutes receive their allotment from the NIH Director in 13 categories, each broken down by number of awards and dollar amounts as determined by the OMB.

We do not believe that the OMB has the scientific expertise and outlook to be making these kinds of decisions. These decisions should be made by the individual institutes and their advisory councils, with input from the biomedical research community. Even though institute directors have some reprogramming authority, it is our understanding that use of this authority has been discouraged under this new system.

The heart association believes that the programs of the NHLBI have been highly successful in the battle against cardiovascular disease because of the valuable principles which guide the institute, maintaining program balance. The OMB's new allocation and apportionment procedures are threatening the success of this time honored approach.

The Heart, Lung, and Blood Institute is by nature a clinical institute. In order to maintain balance that addresses needs, as well as clinical aspects of heart, lung, and blood diseases, the institute and its advisory council must be given a proper amount of flexibility to allocate resources where they are most needed, and where they will bring the best results.

I will echo the discussion this morning with regard to the lack of support for certain of the centers. In response to Senator Weicker's question and comments, I would point out that at the Heart, Lung, and Blood Institute, the percentage of individual grants has appropriately risen, but it is now at the level of 70.4 percent, with only 11.7 percent in centers, and 7 percent in other forms of funding, which we believe to be important.

Finally, as an educator, I must emphasize again the particularly deleterious effect of these developments upon the recruitment of outstanding young people, particularly physicians, for careers in research.

Until recently, Congress had moved effectively to stabilize the NIH funding situation, but the implications of Gramm-Rudman for research are not lost upon the best and brightest of our young people. They see

uncertainty, instability, and an erosion of this Nation's commitment to biomedical research.

More than anything else, the scientific community, and particularly potential young scientists need some sense of vision. They need to know where biomedical research is going. They need to know whether they can stake their professional careers upon it.

Dr. Thier, this morning, made reference to the importance of biomedical research support grants [BRSG] to universities. This is a key issue because the $5,000, $6,000, or $7,000 in appropriations to young investigators as part of the BRSG is crucial.

Gramm-Rudman stands as the sword of Damocles over the heads of biomedical research and biomedical researchers. We believe we must have a better vision for our future.

Senator Weicker raised questions this morning about what the role of our scientific community should be in terms of the education of the public with regard to funding cuts. The Board of Directors of the American Heart Association have passed resolutions expressing their deep concern about overall funding, as well as the increasing OMB management of research. Those positions have been endorsed by some 55 affiliates of the American Heart Association throughout the country.

There is a growing sense among the volunteers of the American Heart Association that we must take greater action and bring to the public our great concerns with regard to what is happening to our biomedical research endeavor.

PREPARED STATEMENT

I thank you for the opportunity to appear and to discuss these issues with the committee.

[The statement follows:]

STATEMENT OF DR. KENNETH SHINE

I am Dr. Kenneth Shine, Dean-Designate of the UCLA School of Medicine, and President-elect of the American Heart Association (AHA). The AHA is the only voluntary agency in the United States devoting all of its human and financial resources to one goal: the reduction of premature death and disability caused by heart attacks, stroke and other blood vessel diseases. In accomplishing this goal, we work in partnership with several Federal research, education and prevention programs whose goals are similar in nature. Since 1948, the AHA and the National Heart, Lung and Blood Institute (NHLBI) have been active partners in the battle against cardiovascular disease -- this Nation's leading cause of death. We are very pleased that you have called these hearings. We believe, as you do, that the public should be aware of the impact of the Administration's budget proposals and other management policies on the progress of biomedical research in this country.

Cardiovascular disease is responsible for almost one million deaths each year. Heart disease, stroke and related disorders account for almost as many deaths as all other causes of death (cancer, accidents, etc.) combined. In 1986, the total economic costs associated with cardiovascular disease are estimated to be over $102 billion in direct medical expenses and lost output due to disability and death. However, there is encouraging evidence that we are making progress against these diseases. Between 1964 and 1984 the death rate for all cardiovascular disease declined by 39 percent. The decline in the death rate for coronary heart disease was 40 percent and for stroke, 55 percent. These encouraging downward trends contributed to 76 percent of the decline in overall mortality between 1964 and 1984 in the U.S.

Throughout our 37-year partnership the research, training, education and community service programs of both the AHA and the NHLBI have had a significant impact on diseases of the heart and circulatory system. While AHA continues to dedicate an increasing amount of its budgetary resources to cardiovascular research, we are hopeful that the NHLBI will be able to continue to take advantage of current and future research opportunities in the cardiovascular field. We are becoming increasingly concerned that decisions made by Federal officials for fiscal reasons in the present may have a detrimental long-term impact on the ability of the Institute to do so.

In addition to the Gramm-Rudman funding reductions that have already had a severe impact on NHLBI's programs, we are very concerned with management changes and additional funding reductions that appear on the horizon. Although we have made great progress in the fight

against cardiovascular disease, we must not become complacent because of past accomplishments. Currently it is estimated that over 63.6 million Americans have one or more forms of cardiovascular disease.. In order to continue to have an impact on the downward trend in mortality due to these diseases, the NHLBI has planned to undertake several exciting new activities in FY 1987, including the following:

- continuation of a clinical trial to assess whether intravenous injections of a thrombolytic agent during the early hours of an evolving myocardial infarction is efficacious. This drug therapy will be used in combination with a procedure known as PTCA or balloon angioplasty.
- a study of the mechanisms that underlie normal cardiac morphogenisis in order to increase understanding of the etiology and pathogenisis of congenital heart failures.
- a clinical trial to assess behavioral and lifestyle interventions contributing to an individual's successful adjustment after coronary artery bypass graft (CABG) surgery and to identify operative, clinical and other factors that may predict early and late graft narrowing and occlusion after surgery.
- an investigation into the feasiblity, acceptability, efficacy and safety of dietary intervention in children with elevated LDL-cholesterol levels. Potential adverse psychological responses to diagnostic labeling and dietary intervention will also be evaluated.
- a study to determine whether PTCA is a safe and effective therapy in patients with severe multivessel coronary artery disease. In addition to clinical centers, the program will also establish a Data Coordinating Center and a central Angiographic Care Laboratory.

These are but a few examples of NHLBI's planned program initiatives for FY 1987. We are very concerned that these and others, particularly the planned clinical trials, will not be allowed to proceed due to a lack of necessary funds. The President's FY 1987 budget proposals would require deep reductions in the programs of the NHLBI at a time when research momentum should not be slowed.

The President's budget includes only $785.7 million, an overall reduction for NHLBI of 4.5 percent from the FY 1986 adjusted appropriation level of $822.3 million. In addition, the President has proposed a rescission for the Institute that would reduce the amount of grants the Institute plans to award in FY 1986 from 886 to 817, a decrease of 69 grants. We urge Congress to reject this proposed rescission. It is simply another attempt by the Administration to reduce the number of grants NIH can fund below Congressionally-mandated levels. The programmatic impact of the President's proposed 1987 budget on NHLBI will be devastating:

- The Institute will be able to fund only 802 new and competing research project grants as compared with the 886 grants that it funded in 1986. Funding for

noncompeting research projects will have to be negotiated downward an average of 11.5 percent.

- The Institute's research centers programs will have to be reduced significantly. In 1986, the Institute allocated $82.8 million for its research centers program. It is estimated that in order to continue this same level of activity in 1987, the Institute would need approximately $93 million. The President's budget, although it calls for the same number of centers to be funded, provides only $75.7 million for this purpose. Centers are unique in their ability to combine a basic science focus Centers are unique in their ability to combine a basic science focus and a clinical research focus which results in rapid translation of important findings into clinical applications. We believe it is highly unwise to underfund such programs.

- Under the President's budget the dollar level and number of research career awards will be held constant -- 364 awards and $21.9 million. In addition, the number of full-time training positions will have to be reduced from 1,627 to 1,500, a decrease of 127 positions. Should this short-sighted approach of level-funding of cardiovascular research training continue, we may not be able to meet future research manpower needs.

- While the amount provided by the President's budget for research contracts, $51.9 million, is a slight increase over the FY 1986 level (approximately $1.1 million), it is far below the level required to maintain current and projected contract activities for FY 1987-- approximately $75 million. The primary reason for the needed increase in FY 1987 is that the phase in which many of NHLBI's contracts will be is the more expensive recruitment phase rather than the initial phase as they were in FY 1986. Several research contract programs would have to be delayed or eliminated should they be funded at the level proposed by the President. When one takes into account the amount of time and resources that would be lost due to a cancellation of currently-funded contracts, it would amount to a significant waste of biomedical research dollars.

- The President's budget completely eliminates NHLBI's funding for construction grants. For the first time in recent years, in FY 1985 Congress provided funding to the

Institute for the much-needed renovation of laboratory facilities. We believe that this funding, at a minimum, should continue at its FY 1986 level of $3.2 million.

- And finally, the intramural research program of the Institute will have to reduce operating costs by as much as 25 percent under the President's proposed budget.

In order to illustrate the true impact of these proposed budget reductions we would like to highlight one important program area -- cholesterol research and education -- at NHLBI. For over 25 years, the AHA has advised physicians and the public about the merits of a low-fat, low-cholesterol diet as a means of reducing the risk of coronary heart disease. We are very excited about NHLBI's new National Cholesterol Education Program (NCEP) which is modeled after its highly successful National Hypertension Education Program. The area of cholesterol research and education is a prime example of an area where AHA and the NHLBI can work in a cooperative manner to tackle an important public health problem.

However, several program activities in this area are threatened by budget reductions in FY's 1986 and 1987. In the area of cholesterol research, over $4 million in grants has been approved in FY 1986 but will not be funded as a result of budget reductions. One important workshop on the treatment of severe hypercholesterolima has been cancelled, and another on the impact of dietary cholesterol on plasma lippoproteins and atherogenisis is in jeopardy. Also in jeopardy is the Institute's ability to assist the Centers for Disease Control in the implementation of the Cholesterol Standardization Program. This effort is crucial to taking steps to make clinical laboratories more consistent and accurate in the measurement of cholesterol levels and represents one of the early priority activities of the National Cholesterol Education Program.

With regard to planned cholesterol research activities in FY 1987, proposed budget reductions will endanger several promising areas of investigation including the use of non-human primates to obtain a better understanding of the relationship of cholesterol and atherosclerosis; a clinical trial to study the effect of postmenopausal estrogen use on coronary heart disease in women; research into the effects of dietary factors on lippoprotein structure and metabolism; and research into the relationship between the Omega-3 Fatty Acids and atherogenisis. In addition, a number of planned cholesterol workshops may not be held due to a shortage of funds.

In the areas of cholesterol education, in FY 1986 the Institute's cholesterol-related publications have been reduced significantly in number. In addition, the Institute has had to reduce its exhibiting schedule and its ability to respond to requests for spokespersons to talk about the NCEP at various conferences and meetings because of a reduced travel budget. A workshop to stimulate both intervention and research related to cardiovascular risk reduction at the worksite may not be held as well. In FY 1987, the Institute will have to reduce in scope some major activities that are already underway such as the major support services contract for the NCEP and the contract to develop broadcast and print materials to carry the Program's message to the public.

The AHA believes that the Institute's efforts in cholesterol and education research should not be sidetracked or slowed at this critical time. Any reduction in effort as a result of a lack of funding in FY's 1986 and 1987 is most unfortunate and would ultimately lead to increased health care costs for the Nation.

The AHA believes that the President's budget request for the National Institutes of Health is highly inadequate. Adequate funding of research is not only an investment in this Nation's future health but produces significant savings in health care costs as well. Generally it has been estimated that for each dollar spent in biomedical research, there is a return of from $10 to $16 in costs due to medical care. Specific examples of advances in the cardiovascular field which have led to significant cost savings are advances in coronary artery surgery research and percutaneous transluminal coronary angioplasty (PTCA) which have resulted in annual net savings to the Nation of over $654 million.

We will be appearing before your Committee later this month to make our specific funding recommendations for the NHLBI. At this time we would like to highlight some of our concerns regarding the increasing involvement of the Office of Management and Budget (OMB) in the management activities of the National Institutes of Health.

As we understand the situation, as of August, 1985 the OMB instituted a new mechanism for apportioning funds to the National Institutes of Health (NIH) which, in turn, required the Office of the Director of NIH to adjust its allotment procedure to the individual institutes. Prior to August of 1985, OMB apportioned funds to the NIH by institute total and then the Director of NIH alloted funds to the individual institutes with only two

categories earmarked -- SBIR funds and consulting services. Allocation among programs of the remaining, and largest, part of the institutes' budgets was left to the individual institutes. Now the Institutes receive their allotments from the NIH Director in thirteen categories, each broken down by number of awards and dollar amount as determined by the OMB.

We do not believe that the OMB staff has the scientific expertise and outlook to be making these kinds of decisions; these decisions should be made by the individual institutes and their advisory councils with input from the biomedical research community. And even though institute directors have reprogramming authority, it is our understanding that use of this authority has been discouraged under this new system.

AHA believes that the programs of the NHLBI have been highly successful in the battle against cardiovascular disease because of the valuable principle which guides the Institute -- maintaining research program balance. While the cornerstone of its program is basic research, the Institute's staff, Advisory Council and the scientific community over the years have also stressed the importance of other program mechanisms such as clinical trials, population studies, specialized centers of research (SCORS), national research and demonstration centers, research career and training awards and development contracts. This balanced program approach has enhanced the NHLBI's reputation as a world-wide leader in cardiovascular research.

The OMB's new allocation and apportionment procedures are threatening the success of this time-tested approach to research. In addition, it is our concern that a continual focus on the number of grants to be funded by the Institute may also jeopardize the success of other program mechanisms. For example, in 1980, 58 percent of NHLBI's extramural research budget went towards research grants, 14 percent went towards research centers, and 17 percent went towards clinical trials. In 1986, these same programs mechanisms received 70.4 percent, 11.7 percent and 7 percent respectively of NHLBI's extramural research budget. This is a very disturbing trend indeed. The NHLBI is, by nature of the disease categories under its research mandate, a "clinical institute." In order to maintain program balance that addresses basic research needs as well as the clinical aspects of heart, lung and blood diseases, the Institute and its Advisory Council must be given the proper amount of flexibility to allocate resources where they are most needed and where they will bring about the best results.

Recently, both the AHA Board of Directors and the NHLBI Advisory Council passed resolutions expressing their concerns regarding the new role of the Office of Management and Budget (OMB) in determining and proscribing line items in the budget of the National Institutes of Health (NIH) and individual institutes. Copies of these resolutions are attached to this statement. The AHA believes that micromanagement by a nonscientific agency such as the OMB adversely preempts the traditional flexibility of the NHLBI, its Advisory Council and the scientific community from participating in the setting of priorities for biomedical research.

As an educator I must emphasize the particularly deleterious effects of these developments upon the recruitment of outstanding young people for careers in research. Until recently Congress had moved effectively to improve the stability of the NIH funding situation. The implications of Gramm-Rudman for biomedical research are not lost upon the best and the brightest of our young people. They see uncertainty, instability and further erosion of this Nation's commitment to biomedical research. More than anything else, the scientific community, and particularly potential young scientists, need some sense of vision. Where is our biomedical research establishment going? When we ask young people to determine their professional careers, what is their future? Gramm-Rudman stands as a sword of Damocles over the heads of biomedical research and biomedical researchers. We must have a better vision for the future.

Again, I want to thank you for the opportunity to raise these issues and I would be happy to answer any questions you may have.

Senator HATFIELD. Thank you, Dr. Shine.

On page 1, where you refer to the statistics between 1964 and 1984, the death rate of all cardiovascular disease declined by 39 percent. Then I believe you used a figure of $68 billion. Is that what you would call a savings because of the decline?

Dr. SHINE. The best figure we have at the present time is our contemporary cost, which is about $102 billion. If you assume that there had not been that kind of decline, then that cost, instead of being $102 billion, would be $170 billion.

Senator HATFIELD. In other words, that is an equivalent to that kind of a savings because of that decline, directly related to that decline.

Dr. SHINE. That is right. It is much as Dr. Thier was talking about this morning. If you do things well, you don't see or hear about it because it disappears. Those are costs that have disappeared because of those decreases in morbidity and mortality.

Senator HATFIELD. I always like to have both the humanitarian statistic as well as the economic statistic. Sometimes, some minds that we have to try to communicate with only respond to the dollar and economics of it, and others respond to the pain and suffering, the quality of life approach. It is very helpful to have both.

Let me just comment further on the matter of education of the public.

We constantly are finding ourselves in a battle position where we are recommending out of this subcommittee, and the full committee, a certain figure for certain categories of programs, in this case for medical research. We will ultimately evolve a proposal, and this proposal will then probably be challenged by the administration, if I can predict the events down the road correctly, and/or certain elements within the Congress who represent the perspective of the administration that we have to reduce these programs in order to make more money available for other programs.

At that point in time, we will have a specific rallying point. These resolutions that have been passed in general about the President's budget are helpful, but really the need will be to mobilize public opinion at that point in time, when we are ready to move to the floor and engage in the battle.

I am hopeful that our relationships and communications, particularly, will be such that we can then give you the bugle call, and call you to arms to mobilize these very people out to their own Senators and their own Representatives, because that will be the real call for public opinion to come to play.

Dr. SHINE. I would agree, Senator. At the same time, our feeling has been that the educational process has to begin as early as possible, so that when the bugle call comes, people understand what the issues are, and can respond in an appropriate way.

It is an interesting dilemma for the voluntary health agencies because, obviously, our principal concern is in reducing death and disability by research and public education, but I think that it is becoming increas-

ingly clear that the voluntary health agencies must take positions with regard to the funding of that since that is such a critical element of whether we will be sucesssful or not.

Senator HATFIELD. That is right. But you see, we have to move from the general of mobilizing indignation, or outrage, or all of those other things, down to the very specific point of the battlefield. Sometimes there is a slippage between those two efforts because, in part, the public has to have something very specific in instruction of how to make its voice heard. They have to be able to refer to a bill, to a measure, to a particular vote that is coming up, and that has to be not only to inform them of that, but then the name of the precise individual with whom they can communicate, particularly from their own States. Then, to extrapolate further, they need the names of the candidates running for reelection this year, because that is when they are most responsive—when we are most responsive.

If you will excuse me, doctor, I will run and vote, and then come back. I want to hear your testimony, if you will be patient with us.

[A brief recess was taken.]

STATEMENT OF DR. GEORGE PALADE, WINNER OF THE NOBEL PRIZE FOR MEDICINE, AND PRESIDENTIAL MEDAL FOR SCIENCE

Senator HATFIELD. Dr. Palade, we are ready now to receive your testimony, and your impressive résumé with all of the recognition, national and international, will be placed in the record.

Dr. PALADE. Thank you, Senator. Let me start by thanking you for giving me this opportunity to testify before you and your subcommittee on the question at hand, which is the question of the Presidential budget.

Senator HATFIELD. Would you pull that a little closer to you, Dr. Palade, the acoustics in this room are very, very poor. We did not have a good engineer for this, I am afraid, they are all out at the Pentagon.

[General laughter.]

Dr. PALADE. While I have been active, and I am still active in basic biomedical research, I am going to talk from this vantage point. In addition to this, my relations with the National Institutes of Health have been primarily with the National Institute of General Medical Science. Again, it is from this point of view that I am addressing the issue and the discussion.

It was already mentioned, but it definitely deserves to be stressed, that we are in a unique situation in the history of biomedical sciences and biomedical research. At no other time in the history of this scientist have the opportunities been so great, so promising, so clearly open in so many directions, and in such a depth.

In contrast to the opportunity curve, which promises to go upwards for at least two or three decades, if not more, we are looking at the other curve, which is the curve of the support given by the Federal Government to basic research. This curve is going down year by year, and when it comes to the Presidential budget for 1987, the drop is alarming. This is what we are trying to address.

Now, you realize that between these two curves, there is a big angle and a large area. That angle is the index of our lost opportunities, and it is at the same time the index of the opportunities that will be used by our competitors, friendly or unfriendly, which can capitalize on what we have realized already, but we cannot push through because of lack of proper support.

Now, no logically organized, rationally organized, or efficiently run business would behave in this way. In other words, the disregard of opportunities for the sake of the emergencies of the moment does not make sense.

The scientific community is clearly aware of the situation, but we should realize that it is not only at this level that the situation is rather well understood. It is also at the level of the administrators of science. The strongest voice in support of a change in the policy of the Government comes from Erich Bloch, the Director of the National Science Foundation, who is advocating an increase by 50 percent of the funds directed by the Government in support of basic research across the board.

It is not only the Director of the National Science Foundation who recognizes properly the situation, but it is also the Scientific Advisory Board of the President, which came with exactly the same figure, 50 percent increase in funds allocated to basic research.

Now what is the situation as far as biomedical research is concerned?

We are not looking at any kind of increase, and definitely not an increase of that order. We are looking at a steady decrease.

Let me look at a few figures to indicate where we stand. I am part of a delegation for basic research, and with that delegation, I came a number of times in the past to participate in hearings in Congress, the Senate, and the House of Representatives.

That delegation decided, 1 year or so ago, that a long-range plan is needed for the support of basic biomedical research in this country. It came up with the idea that, as a reasonable compromise between budgetary restrictions and the need of growth justified by the opportunities I was mentioning, we should have a program that will arrive at the steady state of about 10,000 new research grants per annum.

At the present the situation is as follows: Last year, NIH supported about 6,000 grants, the figure is still hazy. The Presidential budget for 1987 will allow the support of 5,100 grants of this category, which is new and competing grants. Please notice that the 10,000 figure advocated by the delegation for basic research comes very close to the 50-percent increase in support of basic research, including biomedical research, from the National Science Foundation and the Scientific Advisory Committee of the President.

In addition to the fact that money earmarked for grant support, individual grant support, training is also affected by the reductions. Last year, we had 10,000 people under training in different categories, and we don't have to go through the details. The 1987 budget provides for 9,100 new trainees, which is a very substantial reduction.

The NIH budget in 1986 was $5,660,000. The Director of NIH recommended, for 1987, a budget of $6,400,000,000. The Presidential budget for 1987 is $4,930,000,000. So we are clearly going down in funding, numbers of research projects, and the number of trainees. But we are going down in many other indices.

This is the percentage of the national gross income or product that is earmarked for research, including biomedical research, which is going down in this country and is going upward in other countries—the percentage of money allocated to research by comparison with the total health budget of the Nation. Senator Weicker mentioned that $2,000 is spent per person per annum for medical care, and only $25 per person per annum is spent in research.

What we have to realize is the fact that the research programs which were supported primarily by NIH and by NSF have produced the present situation in which the opportunities in all directions are impressive, if you like, amazing, not only in prenatal diagnosis of congenital diseases, but also in cardiovascular disease, also in neoplastic diseases, and also, to some extent, in mental diseases.

If we go now to basic research, we were never closer to understanding basic phenomena, important phenomena, like how cells control the differentiation, or how an egg finally develops in an organism that can become, in time, either a scientist or a Senator.

We are on the threshold of making extremely important advances in biomedical findings, yet what we should realize is that the money invested there has had an influence far beyond the field of biomedicine. It has affected, to a very large extent, animal agriculture, and plant agriculture, not to speak of the pharmaceutical industry. It is affecting now the industry at large to the extent that $40 billion per annum is generated in this country as a result of nonmedical applications of research done either at NIH or NSF biomedical programs.

This is where we really stand. So when the Director of NIH comes and pleads—he is not supposed to plead, excuse me. When he says that in his professional judgment, the budget for NIH for this year should be $6.4 billion, this is a minimal estimate, definitely a minimal estimate, and should be considered as such.

Our delegation has studied in detail the budget, and believes that NIH, in order to be able to carry through its mission, needs a very clear budget of $6.7 billion in 1987. I know you can see the difference in what we believe is reasonable, but it is not at the 50-percent increase advocated by Erich Bloch, or by the Scientific Advisory Board to the President, and what the administration recommends.

There is another problem, which is quite important. The President, in his address when he gave the National Medal of Science, indicated a deep sympathy and interest of the administration in basic research, and he indicated that this year his budget provides a 24-percent increase in basic research. This 24-percent increase in basic research, this indicates very clearly what is the disproportion between basic research applied to defense problems, and basic research applied to civil needs, including

biomedical research, where we have been cut by 5 percent this year, and will be cut by more than 10 percent next year. Therefore, this makes the disproportion between minus 5 percent and plus 24 percent.

Of course, I am not competent to advocate support or not support basic research for military purposes, but what I can definitely advocate, for the sake of the future of this Nation, is basic research on a more balanced basis for civil needs, and especially for biomedical science.

Let me point out that we should not concentrate exclusively on individual research grants, although these individual research grants have been the motor of our progress over the last three decades. We should realize that the infrastructure is suffering at present, and this infrastructure is not only equipment, it is in addition to the other facilities. For example, animal facilities which are now the object of considerable public interest, and which, at present, are underfunded and undersupported. But the technologies developing at present are such that many other instruments of support will be needed, for facilities, for protein chemistry, nuclear chemistry, regional and national resources for centers for producing and disposing of transgenic animals, or for creating libraries for genes, and DNA molecules, and quite a number of others.

We have to maintain our focus on individual grant support because this is what past experience tells us we should do, but we should also take care of the infrastructure considering all of the facilities that are needed for research.

PREPARED STATEMENT

I am not going to cover other issues because I believe I have already spoken too long, but I would be happy to answer questions.

[The statement follows:]

STATEMENT OF DR. GEORGE PALADE

By most measurements, the United States ranks first among nations of the world in its commitment to combat disease. This first rank was achieved in part because U.S. scientists, supported by their government, have exercised free initiative to tackle the most interesting and exciting scientific challenges before them, an effort that has led young people to choose science as a career goal because of the intellectual rewards. This is especially true in basic biomedical research, an area in which American scientists have advanced ahead of their colleagues in all other countries.

The results of this commitment to basic research can be measured in the improvements to the length and quality of our citizens' lives. It has also given rise to a valuable national resource: great and growing biotechnology and pharmaceutical industries.

American leadership in the health sciences is not merely scientific and economic, but moral as well. Other nations look to the United States for solutions to their own health problems.

But biomedical science in the United States is in crisis:

> **It is choked at the top and there is no opportunity for expansion. The contributions that could be made by many fine scientists are ignored and young people, sensing a weakening of national commitment to excellence, are looking elsewhere for careers.**
>
> **Health costs are out of control and without strong resolve and the charting of a clear course toward solution, the health of many of our citizens is in jeopardy.**
>
> **Without solid support for our biomedical community, we have already begun to yield to competing nations the leadership role we have taken for granted, one that has provided not only improved health for most of us, but economic rewards as well.**

The climate that supported the U.S. rise to its leadership position began at the end of World War II, when the nation acquired its first experience with managing major scientific efforts. Prior to World War II, Europeans made most of the critical advances in health science. But the climate that nourished the health sciences is changing. The cost of doing basic research and developing improved health methods is rising, so competition for funds from federal granting agencies is increasing also. This increased competition ties the hands of some workers, forcing them to channel their research into those areas for which funds have been appropriated, setting aside research that may have been more promising. Many in government would slow the advance of basic research in exchange for short term improvements in the federal budget deficit.

It is time for those who guide our nation's science policy to take stock and determine the nature of the science establishment in the year 2000. At minimum, by 2000 the U.S. biomedical system should have:

> **Enunciated a strong, clear intent to be second to none in combatting disease, particularly those that kill and maim or shorten and diminish life for our citizens.**
>
> **Made a clear policy statement that we will have organized our biomedical science establishment so that it will have reached "steady state" -- that is, we will have stabilized so that the number of good young scientists entering the field matches those retiring; our support structure will be in good repair with new equipment coming in on a regular basis to replace the faulty and obsolete.**
>
> **Let the world know in certain terms that a significant portion of our research capability will work on major diseases that afflict Third World nations.**

Created a business climate that will insure that our pharmaceutical and biotechnology industries can thrive.

The biomedical community today is one that is awkwardly skewed, with the bulk of researchers in their 30s and 40s. Few retire so that with the current limit on the absolute number of NIH grants, our researchers will gradually get older and there will be few young people coming along to replace them. This is a situation that would bode ill for any field of endeavor. For science it is national suicide, because we need our young people not only for the many long hours of low-paid dedication they give to their jobs, but we need them for their ideas, for in biology and medicine many of the good new ideas come from graduate students and postdoctoral fellows.

For this reason alone, we must expand the number of research grants awarded by the NIH and assure that each grant contains adequate funds to complete the proposed research. But we must also recognize that our resources are not limitless so our expansion must be measured. We believe that the United States should issue an increased number of grants each year until, in the year 2000, the total is 10,000. This is a number warranted by the number of scientists of exceptional quality who will be available and by the scope of the research effort that can be managed. It is a number that need be increased no further in the foreseeable future. Funding at a reduced level is not an appropriate policy, but rather an inappropriate accountancy measure.

SO THE UNITED STATES IS AT A HEALTH CROSSROADS:

If we are to be in the position of leadership described here by the Year 2000, we must begin to make decisions now to repair and improve the machinery of our health sciences establishment, to provide the trained people and resources that will place our health sciences system in a "steady state" operation, in which young scientists replace those who retire and new laboratories come "on stream" to replace those that are obsolete, where ideas move quickly from university or NIH laboratory to hospital or to pharmaceutical or biotechnology company.

While we continue to lead, we are ailing. Our institutions are in large part old and in need of renovation. We have limited the number of scientists participating in health research so severely that in the next generation many who would have been talented U.S. biologists or medical researchers may choose to be computer scientists or lawyers. We have not looked ahead, but have planned from year to year and as a result the means to continue at the cutting edge of science may soon not be at our disposal.

How easily we forget that until three decades ago, polio stole away the summers of much of our society and left thousands horribly crippled. It was basic research that provided the tools for a scientific onslaught that wiped out polio in this country. Despite our major scientific advances, in the United States today 60 million suffer from cardiovascular disease; 400,000 die each year from cancer; 2,000,000 elderly Americans have Alzheimer's disease, 300,000,000 worldwide are afflicted with malaria; and 2,000,000 children--and many more adults--have severe mental disorders. The list is endless. But what is happening to our basic research capability today? Are we in fact dismantling through neglect the system that provides our best hope for combating disease as well as providing major contributions to such other societal problems as hunger and pollution?

Today there are major research efforts underway that promise to provide relief soon against hepatitis and herpes, and in the longer term against cancer, AIDS and heart disease. But, our scientific apparatus is stumbling and we may have to prolong the time necessary to control these diseases that are currently so widespread in American society.

The U.S. Commerce Department forecasts a worldwide market for biotechnology products of $100 billion by 1990, up by a factor of ten. Japan and West Germany devote higher portions of their gross national products to civilian R&D than we do. From 1973 to 1982 the U.S. proportion of science and technology in biomedicine remained constant.

It costs $2,000 per person each year for health care for Americans. Annual federal investment in medical research is only $25 per person.

Our national goals today and in the Year 2000 should be to:

Prevent and cure disease;
Foster industrial innovation;
Enhance our international prestige;
Educate a new generation of scientists.

If we are to be in that position in the Year 2000, then we need a cogent plan now that will, by the Year 2000, do the following:

1. Gradually increase the number of new NIH grants funded each year to 10,000 and provide the funds to support them productively. The present maximum of 6000 excludes large numbers of talented scientists.

2. We must recognize that modern equipment and instrumentation is extremely costly and work out new grant mechanisms that will purchase equipment for individual laboratories and provide for joint use.

3. Older laboratories need to be renovated now and a plan must be placed in force to provide for all laboratories to be renovated every 20 years.

4. To accommodate the additional scientists who will be supported by an expanded grant system, our laboratories will need to be enlarged, and perhaps some new ones built, over the next 15 years. Since it takes five years to design and build a laboratory building, funding for the first of these buildings must come soon.

5. The strength of our scientific establishment depends upon a firm national political commitment that will imbue students with the feeling that their country wants them to put heart and soul into a struggle to improve the health of all citizens, and will honor and respect them for their efforts.

WHY INCREASE THE NUMBER OF GRANTS TO 10,000?

For students planning careers, medicine, law, computers or business are appealing. They are reasonably assured of making a comfortable living, both near term and in the more distant future, while working in a stable field that does not confront them repeatedly with career ending threats. Not so in biomedical research. Since only 15-17,000 NIH grants are in force at any one time and there are three or four times that many researchers, there is little room at the entry level. We estimate that our system can support perhaps twice as many able researchers as are now supported. Presently only 30 per cent of grant applications are awarded. Those responsible for the other 70 per cent keep reapplying until they are discouraged and abandon their careers. In short, there is much good science not being funded. An increase in the award rate in synchrony with an increased number of new grants should result in perhaps twice as many able investigators working in the field by 2000. This would salvage a large pool of native talent and trained skills, encourage the more adventurous scientists to take risks on innovative ideas and encourage the nation's youth to plan careers in science.

HOW MUCH GOVERNMENT CONTROL CAN WE HAVE?

While effective long-range planning is mandatory, we must not lose sight of the fact that our leadership position came about because our scientists have been unfettered. Answerable only to their peers, our scientists were able to pursue their best ideas, rather than try to mold their research to conform to a government-mandated program. The Soviets tried it the other way, following Lysenko's lead, and today have no significant biomedical research underway, and certainly no biotechnological industries. Long-term planning means keeping the best of the United States'

present highly successful biomedical science enterprise intact while implementing reasonable measures to insure its stability and flexibility. Too much planning could be more destructive than the present lack of long-term thinking.

LONG-TERM COMMITMENTS THE GOVERNMENT SHOULD MAKE

The National Institutes of Health is the flagship of our nation's biomedical research effort. It is unique in the world. It provides leadership and quality control for scientists in universities and independent laboratories throughout the nation and its own laboratories produce some of the finest research in our nation. It is non-political, professional and dedicated. Yet it must exist in a political climate that requires compromise and a willingness to "play the game," both anathema to the sponsorship of good science. The NIH must be insulated from some of this pressure so that the quality of the science it supports is not diluted. The same is also true of many other agencies in government that make up the complex fabric of American health sciences: the Alcohol, Drug Abuse and Mental Health Administration; the centers for Disease Control; the Food and Drug Administration, and there are others. Some institutional arrangements that can be made are:

1. Protect NIH's prime focus on basic research. There is a tendency in our country to create specialized institutes to focus on single diseases or problems. This dilutes the NIH mission, which is to foster basic research to provide a floor of understanding that will lead, with time, to cures. The long-term trend should be to take those specialized institutes that outrun their missions and fold their research back into the mainstream, while resolving not to create new ones.

2. Provide the NIH director with increased discretionary authority to encourage flexibility and faster response. At present, the various institutes in the NIH are nearly autonomous and the director does not have the funds or the authority to shift funds to apply to problems of the moment. While some restrictions upon the director are necessary to avoid violent swings in research directions, the director needs to have more power to influence the course of research than is the case at present.

3. Review the roles of all biomedical agencies, restructuring where they are in conflict, redundant or unnecessary and providing strong multi-year budgets to sharpen and enhance their productivity.

4. Institute a plan that will progressively strengthen the basic peer-review system for grants, while reducing paperwork and other red tape. This can be done in part by encouraging a lengthening of the average term of grants, particularly initial grants, which are currently for three years. With these grants, researchers find themselves able to work for only two years before beginning the grant application program over again, a lengthy, tedious, frustrating and non-productive process. A more realistic plan would be to make the norm of all NIH project grants five years of support, while keeping in place current mechanisms for review.

5. Establish a series of goals over the next 15 years for construction of new facilities and for purchase of major equipment, as well as for renovating existing facilities.

THE MATTER OF PRIORITIES

Care must be taken in setting long-term goals. Because of the nature of the scientific search process, it is often impossible to define priorities and directions with precision. Science determines its own goals as it proceeds from one discovery to another. To focus on priorities and directions--as opposed to talent and creativity—can be retrogressive, returning government to an unenlightened

"disease-of-the-month" mythology that would target individual diseases and allocate money for their defeat. It puts politics into the business of determining directions for research, a sure formula for disaster.

To put ourselves in a winning posture again, only one priority needs to be raised on our national agenda:

WE RESOLVE TO CONTINUE OUR COMMITMENT TO ALLEVIATE HUMAN SUFFERING.

Medical history shows that scientists free to pursue their own course of scientific inquiry will produce the tools needed for the task.

Senator HATFIELD. Thank you very much, Dr. Palade. It is very helpful. I, again, appreciate your point on the deteriorating and crumbling infrastructure.

It is an interesting point that out in Topeka, KS, about 33 years ago, on the 27th this last February, President Eisenhower launched the Interstate Highway System as a part of our national defense program, not as a transportation system, because he recognized the fundamental part of the infrastructure of the Nation as it related to our national security.

Oftentimes, we fail to view those supporting, auxiliary infrastructure parts of any effort that has a high, visible superstructure. Without that strong infrastructure, the Nation can be weakened, or the whole enterprise of research can fail or be weakened without attention to the infrastructure there.

I think also President Eisenhower recognized the importance of the health of the people as a part of our national defense. There, again, where we are in this contest today between increasing a $286 billion budget by 8 percent in real dollars for fiscal year 1987, at the same time you talk about the decreases that are occurring in the NIH budget. Unfortunately, we have a myopic perspective today that the Nation's security is funded only in the Defense Subcommittee, whereas, really, the Nation's security is being funded here every bit as much if we have a perspective and an understanding of the comprehensiveness of our Nation's security.

Dr. PALADE. I fully agree with what you are saying, Senator. The further details, what our delegation suggests, in terms of budgetary allocations for NIH in the 1987 fiscal year, are available and can be provided to the subcommittee.

Let me point out something, which appeared in the discussion this morning, the fact that scientists are not able to influence the public. I believe, yes, the scientists could do better than they do at present, although my impression is that the performance on the part of the scientists and the response from the public have been improving over the years.

For example, the Harris poll last year indicated that 80 percent of the public will be in favor of support of basic research at an increased level even in a period of budgetary stringency. The Harris poll was in the Washington Post, therefore, it should be known.

But in this situation, we are really dealing with dialog. One dialog is the reaction of the public as influenced by the scientists. Another element in the dialog is the leadership which comes from the political leaders of the Nation. That leadership, somehow, is missing. We cannot blame everything on the public.

Fortunately, there is leadership in Congress. Without this leadership in Congress, we would be in a considerably worse situation than we are at present. We hope that that leadership will continue.

The issue in our mind is how to go beyond this level, and to convince that the need for leadership exists across the level of the political leadership of the country.

Senator HATFIELD. Senator Inouye, do you have any comments that you wish to make?

Senator INOUYE. I am pleased and privileged to be in the presence of such a distinguished panel. I am sorry that I wasn't here earlier, but we have a little island called Airports.

Senator HATFIELD. Ten days with that little island called Airports.

I want to say that, certainly, Senator Inouye qualifies as part of that congressional leadership that you referred to. We are very, very grateful for his help on this subcommittee.

Gentlemen, we are grateful for the efforts that you have made and the time you have given to come here and to assist us. The data is most important. We feel that the superiority of our argument will depend upon the data we have, and you have provided us with that. It gives us a great optimism that we are going to win this battle with this kind of ammunition. This is the kind of warfare I love to engage in.

CONCLUSION OF HEARING

The subcommittee will now stand in recess.

[Whereupon, at 11:22 a.m., Friday, April 11, the hearing was concluded, and the subcommittee was recessed, to reconvene subject to the call of the Chair.]

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